Treating the underlying cause is another first worth remembering.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

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See KALYDECO Study Results

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Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible.

Age: 1 month and older*

Mutation 1: Mutation 1

Mutation 2: Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

You can view the full list of eligible mutations here.

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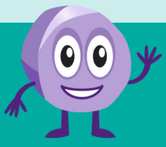

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- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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  - runny nose
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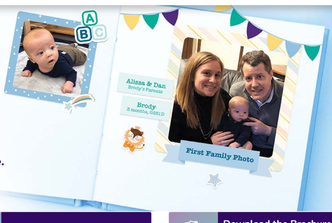

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1 month and older*	F508del	F1052V	Submit

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Based on the information you entered, you may be eligible for KALYDECO.

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Here is some information about KALYDECO that may be helpful:

See the Clinical Study Results | Learn About Safety and Side Effects | Watch How KALYDECO Works

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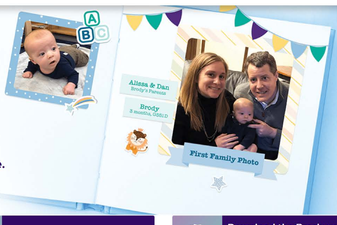

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Neither CF gene mutation you entered is eligible for KALYDECO.

Talk with your healthcare provider to discuss your CF care plan and treatment options that may be right for you.

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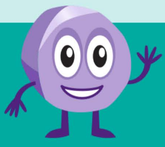

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Learn how to enter 2 or more mutations.

Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

To enter 2 or more mutations into 1 entry field, separate them with a semicolon, space, comma, or forward slash. For example, if your mutations are R74W/V201M/D1270N and W1282R, use the Mutation 1 field to enter: R74W; V201M; D1270N and the Mutation 2 field to enter: W1282R.

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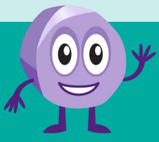

Join Grant the Granule and a family to learn how to give KALYDECO

Step-by-step instructions help ensure you prepare and give KALYDECO oral granules the right way.

WATCH NOW

IMPORTANT SAFETY INFORMATION

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- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
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- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
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  - runny nose
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- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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How KALYDECO® Works

The underlying cause of cystic fibrosis (CF)

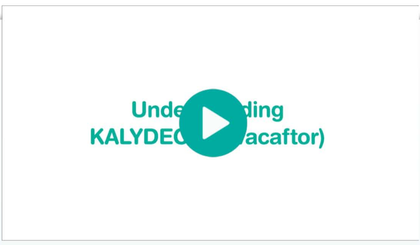
CF is caused by cystic fibrosis transmembrane conductance regulator (CFTR) protein defects. A mutation in the genes of a person with CF may make defective CFTR proteins that:

- Don't open correctly
- Don't get to the cell surface, where they are normally located

A person with CF may make CFTR proteins that have either or both of these defects.

Because of these defects, chloride ions cannot flow freely into or out of the cells as they should, leading to an imbalance of salt and water. This can lead to thick, sticky mucus in the lungs.

See how KALYDECO works



Watch This Video to See How KALYDECO Works

Learn how KALYDECO helps certain CFTR proteins work better.

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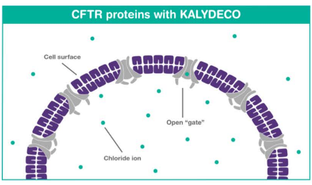
KALYDECO targets the underlying cause



KALYDECO affects gating of the CFTR protein. KALYDECO is used in people age 1 month and older who have at least one mutation in their CF gene that is responsive to KALYDECO.

In patients with a mutation in their CF gene that is responsive to KALYDECO, KALYDECO works to help the "gates" stay open longer, allowing more chloride ions to move into and out of the cells. The movement of chloride ions may help keep a balance of salt and water in the lungs. KALYDECO does not increase the number of CFTR proteins at the cell surface.

What is known about how KALYDECO works was learned from studies conducted in a lab. Keep in mind that results from laboratory studies do not always match how these medicines work in a person. If you have any questions about your KALYDECO treatment, please speak with your healthcare provider.

Patient Stories With KALYDECO
Read stories from the KALYDECO community.

Explore Resources
Brochures and videos to help you learn more about KALYDECO.

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Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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Who KALYDECO® Is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age: 1 month and older*

Mutation 1: F508del

Mutation 2: F1052V

Submit

Learn how to enter 2 or more mutations.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

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Based on the information you entered, you may be eligible for KALYDECO.

Talk with your healthcare provider to see if KALYDECO is right for you.

Here is some information about KALYDECO that may be helpful:

See the Clinical Study Results | Learn About Safety and Side Effects | Watch How KALYDECO Works

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

How KALYDECO Works

Learn how KALYDECO helps certain CFTR proteins work better.

KALYDECO Clinical Studies

Review the results.

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Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

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Age:	Mutation 1:	Mutation 2:	
1 month and older*	F508del	F508del	Submit

Learn how to enter 2 or more mutations.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

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Neither CF gene mutation you entered is eligible for KALYDECO.

Talk with your healthcare provider to discuss your CF care plan and treatment options that may be right for you.

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

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Review the results.

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Mutation 1: test

Mutation 2: Mutation 2 (if known)

Submit

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We're sorry, we do not recognize 1 or both of the mutations you entered.

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You can view the full list of eligible KALYDECO mutations here.

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  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
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The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

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Who KALYDECO® Is For

Check Your Eligibility

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Age: 1 month and older*

Mutation 1: Mutation 1

Mutation 2: Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations.

Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

To enter 2 or more mutations into 1 entry field, separate them with a semicolon, space, comma, or forward slash. For example, if your mutations are R74W/V201M/D1270N and W1282R, use the Mutation 1 field to enter: R74W; V201M; D1270N and the Mutation 2 field to enter: W1282R.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

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We're sorry, we do not recognize 1 or both of the mutations you entered.

Talk to your healthcare provider to discuss your CF care plan. They can help determine what treatment option is right for you at this time.

You can view the full list of eligible KALYDECO mutations here.

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

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711+3A→G*	F311del	I148T	R75Q	S589N
2789+5G→A*	F311L	I175V	R117C*	S737F
3272-26A→G*	F508C	I807M	R117G	S945L*
3849+10kbC→T*	F508C;S1251N†	I1027T	R117H*	S977F*
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W*	R170H	S1251N*
A455E*	G178R*	L320V	R347H*	S1255P*
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q*	T1053I
D110H	G551D*	L1480P	R553Q	V232D
D192G	G551S*	M152V	R668C	V562I
D579G*	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H*	G1069R	P67L*	R1070Q	W1282R
D1270N	G1244E*	Q237E	R1070W*	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D*	Q359R	R1283M	
E822K	H939R	Q1291R	S549N*	
E831X*	H1375P	R74W	S549R*	

*Clinical data exists for these mutations. **See clinical studies**.

†Complex/compound mutations. Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

Minimize List

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KALYDECO® Results

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of **97 indicated mutations**.

Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

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Study 8

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KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine

- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Study 8

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

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KALYDECO can cause serious side effects, including:

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  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

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  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine

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  - rash or hives
  - tightness of the chest or throat or difficulty breathing
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The most common side effects of KALYDECO include:

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  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
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Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Study 8

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

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KALYDECO can cause serious side effects, including:

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  - light-headedness or dizziness
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KALYDECO® Results

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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Study 6

G551D, S549N

Age 6 years and older

Age 12 years and older

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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Especially tell your doctor if you take:

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- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine

- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 6 years and older

Study 2 (age 6 through 11)

G551D

Study 4 (age 6 years and older)

G1244E, G1349D, G178R, G551S, G970R,* S1251N, S1255P, S549N, S549R

*KALYDECO is not indicated for people with cystic fibrosis (CF) who have the G970R mutation.

Study 5 (age 6 years and older)

R117H

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 12 years and older

IMPORTANT SAFETY INFORMATION

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- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

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The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

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Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

Study 1

G551D

Study 7

2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, S977F

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  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Back to all studies

Age 1 month to less than 4 months old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 7 children age 1 month to less than 4 months old.

See the results for children age 4 months to less than 6 months old.

Mutations eligible to enroll in this part of the study were:

Any mutation responsive to KALYDECO.

Mutations included in this part of the study:

4 children had the G551D mutation. The 3 remaining children had R117C, R117H, and S945L mutations.

How KALYDECO was given

Children age 1 through 2 months old who weighed **3 kg (~7 lb) to less than 5 kg (~11 lb)** received **5.7 mg of KALYDECO oral granules every 12 hours.**

Children age 2 through 3 months old who weighed **5 kg (~11 lb) or more** received **11.4 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food.

When they turned 4 months old, their dose was adjusted, if needed, based on weight.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information.

Other study results

Sweat chloride

For children age 1 month to less than 4 months old who took KALYDECO:
Sweat chloride decreased on average by -40.3 mmol/L through Week 24.

(average mmol/L beginning of study was 73.8)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1*).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 1 month to less than 4 months old based on the efficacy shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

VERTEX

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KALYDECO® Results

Back to all studies

Age 4 months to less than 6 months old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 6 children age 4 months to less than 6 months old.

See the results for children age 6 months to less than 1 year old.

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study:

5 children had the G551D mutation, and 1 had the R117H mutation.

How KALYDECO was given

All children weighed between **5 kg (~11 lb) and 7 kg (~15 lb)** and received **25 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments. When they turned 6 months old, their dose was adjusted, if needed, based on weight.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information.

Other study results

Sweat chloride

For children age 4 months to less than 6 months old who took KALYDECO:
Sweat chloride decreased on average by -50.0 mmol/L at Week 24.

(average mmol/L beginning of study was 97.4)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1*).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 4 months to less than 6 months old based on the efficacy shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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KALYDECO® Results

Back to all studies

Age 6 months to less than 1 year old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 11 children **age 6 months to less than 1 year old**.

See the results for children age 1 year to less than 2 years old.

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study:

10 children had the G551D mutation, and 1 had the G178R mutation.

How KALYDECO was given

Children who weighed **7 kg (~15 lb) to less than 14 kg (~31 lb)** received **50 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information.

Other study results

Sweat chloride

For children age 6 months to less than 1 year old who took KALYDECO:
Sweat chloride decreased on average by -58.6 mmol/L at Week 24.

(average mmol/L beginning of study was 101.5)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1*).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 6 months to less than 1 year old based on the efficacy shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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KALYDECO® Results

Back to all studies

Age 1 to less than 2 years old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 19 children **age 1 to less than 2 years old.**

See the results for children age 6 months to less than 1 year old.

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study:

16 had the G551D mutation, 2 had the S549N mutation, and 1 had the G178R mutation.

How KALYDECO was given

Children who weighed **7 kg (~15 lb) to less than 14 kg (~31 lb)** received **50 mg of KALYDECO oral granules every 12 hours.**

Children who weighed **14 kg (~31 lb) to less than 25 kg (~55 lb)** received **75 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed into 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information.

Other study results

Sweat chloride

For children age 1 year to less than 2 years old who took KALYDECO:
Sweat chloride decreased on average by -73.5 mmol/L at Week 24.

(average mmol/L beginning of study was 104.1)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1*).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 1 to less than 2 years old based on the benefits shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

VERTEX

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KALYDECO® Results

Back to all studies

Age 2 to less than 6 years old

Study 6

Study 6 was a 24-week study in which the safety of KALYDECO was evaluated in 34 children **age 2 to less than 6 years old** with cystic fibrosis (CF). All children in this study took KALYDECO. No one in this study took placebo. The primary purpose of this study was to determine the safety and tolerability of KALYDECO.

Mutations eligible to enroll in this study were:

G1244E, G1349D, G178R, G551D, G551S, G970R,* S1251N, S1255P, S549N, S549R.

*KALYDECO is not indicated for people with CF who have the G970R mutation.

Mutations included in this study:

32 children had the G551D mutation and 2 had the S549N mutation.

How KALYDECO was given

Children who weighed **less than 14 kg (~31 lb)** received **50 mg of KALYDECO oral granules every 12 hours**.

Children who weighed **14 kg (~31 lb) or more** received **75 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The type and frequency of side effects for children in the study were similar to those seen in KALYDECO studies with people with CF age 6 years and older.

High liver enzymes were more common in children who had abnormal liver enzymes before starting KALYDECO.

See additional safety information.

Other study results

Sweat chloride

After taking KALYDECO:
Sweat chloride decreased on average by ~45 mmol/L through Week 24.

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1*).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 2 years to less than 6 years old based on the benefits shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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KALYDECO® Results

Back to all studies

Age 6 years and older

Study 2

Study 2 was a 48-week study in which 52 people **age 6 to less than 12 years old** with a G551D mutation took KALYDECO (150-mg tablets) or placebo with fat-containing food every 12 hours. Results were measured at different time points, including 24 and 48 weeks. All people took other cystic fibrosis (CF) treatments except for hypertonic saline through the entire length of the study (48 weeks). The study evaluated lung function (FEV_1*): Other results studied were CF respiratory symptoms, weight, and sweat chloride. The study also evaluated the safety of KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Mutation eligible to enroll and included in this study was:

G551D.

Study results

Lung function (FEV_1)

Lung function increased

12.5 percentage points greater average improvement, compared to placebo through 24 weeks.
10.0 percentage points greater average improvement, compared to placebo through 48 weeks.

Lung function can be measured with an FEV_1 test, which measures how much air a person can exhale in a forced breath in 1 second.

Other study results

CF respiratory symptoms

No difference was seen in respiratory symptoms compared to placebo through Week 48.

Respiratory symptoms are measured by the CFQ-R respiratory domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Weight

Weight increased

About 2.8 kg (~6 lb) on average, compared to placebo at Week 48.

Sweat chloride

After taking KALYDECO:

Sweat chloride decreased on average by -53 mmol/L compared to placebo through Week 48.

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1).**

KALYDECO has also been studied in people age 12 and older who have the G551D mutation. Be sure to review the information on this study in the Age 12 years and older section of this website.

Study 4

In Study 4, 39 people **age 6 and older** who had an eligible CF mutation (listed below) took KALYDECO (150-mg tablets) or placebo with fat-containing food every 12 hours. All people took all their other CF treatments except for hypertonic saline. Each person had an 8-week treatment period with KALYDECO and an 8-week treatment period with placebo. The study evaluated lung function (FEV_1). Other results studied were CF respiratory symptoms, body mass index (BMI), and sweat chloride. The study also evaluated the safety of KALYDECO.

Mutations eligible to enroll and included in this study were:

G1244E, G1349D, G178R, G551S, G970R,† S1251N, S1255P, S549N, S549R.

†**KALYDECO is not indicated for people with CF who have the G970R mutation.**

Important considerations

- **Results for the mutations studied varied by mutation. Not all mutations showed the same level of benefit when taking KALYDECO**
- **Some people experienced less improvement compared to the average for all the people in the study. Others experienced more improvement**
- **Talk to your healthcare provider to learn more about your specific mutation**

Study results

Lung function (FEV_1)

Lung function increased

In the overall population for the 9 mutations studied, people had a 10.7 percentage points average improvement in lung function compared to placebo, from the start of the study through Week 8.

Results varied by mutation.

Lung function can be measured with an FEV_1 test, which measures how much air a person can exhale in a forced breath in 1 second.

Other study results

CF respiratory symptoms

CF respiratory symptoms improved

In the overall population for the 9 mutations studied, people had a 9.6-point average improvement in CF respiratory symptoms compared to placebo, from the start of the study through Week 8.

Results varied by mutation.

Respiratory symptoms are measured by the CFQ-R respiratory domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Body mass index (BMI)

BMI increased

In the overall population for the 9 mutations studied, people had a 0.66 kg/m^2 on average increase in BMI compared to placebo at Week 8.

Results varied by mutation.

BMI is a measure of someone's weight in relation to his or her height. For example, for a 5'4", 110-lb adult, a 0.66 kg/m^2 increase in BMI would be a gain of about 4 lb; for a 4'6", 65-lb child, this would be a gain of about 3 lb.

Sweat chloride

Sweat chloride decreased

In the overall population for the 9 mutations studied, people had a -50 mmol/L average decrease in sweat chloride compared to placebo from the start of the study through Week 8.

Results varied by mutation.

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1).**

Study 5

Study 5 was a 24-week study in which 69 people **age 6 and older** with an R117H mutation took either KALYDECO (150-mg tablets) or placebo with fat-containing food every 12 hours, along with their other CF treatments. The study evaluated lung function (FEV_1). Other results studied were sweat chloride, CF respiratory symptoms, body mass index (BMI), and pulmonary exacerbations. The study also evaluated the safety of KALYDECO.

Mutation eligible to enroll and included in this study was:

R117H.

What was studied

Lung function (FEV_1)

Lung function (FEV_1) was the main measure of this study

Lung function can be measured with an FEV_1 test, which measures how much air a person can exhale in a forced breath in 1 second.

Other measures studied

Sweat chloride
Sweat chloride is a measure of the amount of salt in your sweat. People with CF have high levels of sweat chloride.

Body mass index (BMI)
BMI is a measure of someone's weight in relation to his or her height.

Safety
Safety includes the evaluation of all side effects that occur during a study.

CF respiratory symptoms
Respiratory symptoms are measured by the CFQ-R respiratory domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Pulmonary exacerbations
Pulmonary exacerbations are defined as changes in certain symptoms requiring changes in the use of oral, IV, or inhaled antibiotics.

Some people in this study showed improvement in these measures, but others did not.

- Please talk to your healthcare provider if you'd like to learn about the results of this study

Back to top

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Back to all studies

Age 12 years and older

Study 1

Study 1 was a 48-week study in which 161 people **age 12 and older** with a G551D mutation took KALYDECO (150-mg tablets) or placebo with fat-containing food every 12 hours, along with their other cystic fibrosis (CF) treatments. Results were measured at different time points, including 24 and 48 weeks. All people took all their other CF treatments except for hypertonic saline through the entire length of the study (48 weeks). The study evaluated lung function (FEV_1*). Other results studied were CF respiratory symptoms, pulmonary exacerbations, weight, and sweat chloride. The study also evaluated the safety of KALYDECO.

*FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Mutation eligible to enroll and included in this study was:

G551D.

Study results

Lung function (FEV_1)

Lung function increased

10.6 percentage points greater average improvement, compared to placebo through 24 weeks.

10.5 percentage points greater average improvement, compared to placebo through 48 weeks.

Lung function can be measured with an FEV_1 test, which measures how much air a person can exhale in a forced breath in 1 second.

Other study results

CF respiratory symptoms

8.6 points on average, compared to placebo, from the start of the study through Week 48.

Respiratory symptoms are measured by the CFQ-R Respiratory Domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Pulmonary exacerbations

Pulmonary exacerbations decreased

Nearly **7 out of 10** people who took **KALYDECO** did not have a pulmonary exacerbation, compared to around **4 out of 10** people who took **placebo** at Week 48.

Pulmonary exacerbations are defined as changes in certain symptoms requiring changes in the use of oral, IV, or inhaled antibiotics.

Weight

Weight increased

About 2.7 kg (~6 lb) on average, compared to placebo at Week 48.

Sweat chloride

After taking KALYDECO:

Sweat chloride decreased on average by -48 mmol/L compared to placebo through Week 48.

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1).**

Study 7

Study 7 was an 8-week study in which people **age 12 and older** with 1 copy of the F508del mutation and a second mutation predicted to respond to KALYDECO took either KALYDECO (150-mg tablets) or placebo with fat-containing food every 12 hours. All people took all their other CF treatments. The study evaluated lung function (FEV_1). CF respiratory symptoms and safety were also studied.

In this study, 156 people took KALYDECO (150-mg tablets) and 161 people took placebo.

Mutations enrolled in this study were:

2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, S977F.

Important considerations

- **Results varied by mutation.** Not all mutations showed the same level of benefit when taking KALYDECO
- Some people experienced less improvement compared to the average for all the people in the study. Others experienced more improvement
- This is not intended to represent the full study design or results
- Talk to your healthcare provider for more information

Study results

Lung function (FEV_1)

Lung function increased

In the overall population studied, lung function increased by 4.7 percentage points on average compared to placebo from the start of the study to the average of Week 4 and Week 8.

Results varied by mutation.

Lung function can be measured with an FEV_1 test, which measures how much air a person can exhale in a forced breath in 1 second.

Other study results

CF respiratory symptoms

CF respiratory symptoms improved

In the overall population studied, CF respiratory symptoms improved by 9.7 points on average compared to placebo from the start of the study to the average of Week 4 and Week 8.

Results varied by mutation.

Respiratory symptoms are measured by the CFQ-R Respiratory Domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Back to top

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- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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Especially tell your doctor if you take:

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  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
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- diarrhea
- rash
- nausea
- dizziness

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

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Safety & Side Effects

How the safety of KALYDECO® was assessed in clinical studies

Serious and most common side effects

Additional safety considerations

The overall safety profile of KALYDECO is based on data from 3 placebo-controlled studies. The safety data from the 3 clinical studies were combined and reviewed together, or "pooled," to arrive at the safety profile for KALYDECO.

Across these studies, a total of 353 people 6 years of age and older with the G551D mutation (Studies 1 and 2) or 2 copies of the F508del* mutation (Study 3) in their *CFTR* gene took KALYDECO or placebo every 12 hours with fat-containing food. 221 people received KALYDECO and 132 people received placebo.

***KALYDECO is not approved and is not effective in people with cystic fibrosis (CF) with two copies of the F508del mutation (F508del/F508del) in the CF gene.**

In addition, safety was assessed in the following clinical studies:

- **Study 4**: Study of KALYDECO in 39 people with CF age 6 years and older with a **G1244E, G1349D, G178R, G551S, G970R,**[†] **S1251N, S1255P, S549N,** or **S549R** mutation. People in the study took either KALYDECO (150-mg tablets) or placebo every 12 hours with fat-containing food. Each person had an 8-week treatment period with KALYDECO and an 8-week treatment period with placebo
  [†]KALYDECO is not indicated for people with CF who have the G970R mutation.
- **Study 5**: A 24-week study in which KALYDECO was studied in 69 people with CF age 6 years and older with an **R117H** mutation. People in the study took either KALYDECO (150-mg tablets) or placebo every 12 hours with fat-containing food
- **Study 6**: A 24-week study in which KALYDECO was studied in 34 children with CF age 2 to less than 6 years with a **G551D** or **S549N** mutation. All children in this study took KALYDECO (50-mg or 75-mg oral granules) every 12 hours with fat-containing food. No one in this study took placebo
- **Study 7**: An 8-week study in which KALYDECO was studied in people with CF age 12 years and older with 1 copy of the F508del mutation and a **2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D1152H, D579G, E831X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L,** or **S977F** mutation. In this study, 156 people took KALYDECO (150-mg tablets) and 161 people took placebo every 12 hours with fat-containing food
- **Study 8**: A 24-week study in which KALYDECO was evaluated in 43 children with CF. Nineteen of the children were age 12 months to less than 2 years. Eleven of the children were 6 months to less than 1 year. Six of the children were 4 months to less than 6 months. Seven of the children were age 1 month to less than 4 months. All children in this study took KALYDECO oral granules every 12 hours with fat-containing food. No one in this study took placebo

The safety profile for Studies 4, 5, 6, 7, and 8 was similar to that observed in Studies 1 and 2.

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- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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Safety & Side Effects

How the safety of KALYDECO® was assessed in clinical studies

Serious and most common side effects

Additional safety considerations

Remember, this website is for informational purposes only and is not intended to be a substitute for professional medical advice. You should talk to your healthcare provider about the clinical study results and the possible side effects of KALYDECO.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

High liver enzymes in the blood, which have happened in people receiving KALYDECO.

Your doctor will do blood tests to check your liver:

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Especially tell your doctor if you take:

Antibiotics	Seizure medicines	Herbal supplement
rifampin (RIFAMATE®, RIFATER®) rifabutin (MYCOBUTIN®)	phenobarbital carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®) phenytoin (DILANTIN®, PHENYTEK®)	St. John's wort
Antifungal medicines	**Antibiotics**	
ketoconazole itraconazole (SPORANOX®) posaconazole (NOXAFIL®) voriconazole (VFEND®) fluconazole (DIFLUCAN®)	telithromycin clarithromycin (BIAXIN®) erythromycin (ERY-TAB®)	

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How to Take KALYDECO®

Take KALYDECO every 12 hours or as directed by your healthcare provider

- Taking KALYDECO every 12 hours helps keep enough medicine in the body
- Remember, taking KALYDECO every 12 hours is not the same as taking it twice a day
- Your healthcare provider may prescribe a different dose or frequency for KALYDECO

Always take KALYDECO with fat-containing food

- Fat-containing food helps the body absorb KALYDECO better

  See examples of fat-containing foods.

- Avoid foods and drinks that contain grapefruit, as these may affect the amount of KALYDECO in the body

Take KALYDECO, plus all your other cystic fibrosis (CF) therapies, exactly as your healthcare provider tells you to take them

- Be sure to talk to your healthcare provider before starting, changing, or stopping any CF therapies or other medications, including prescription and non-prescription medicines, vitamins, and herbal supplements

Before you start taking KALYDECO, **be sure KALYDECO is right for you**.

To learn how to take KALYDECO oral granules or tablets, from how they're supplied to step-by-step instructions, choose one below.

How to take KALYDECO oral granules | **How to take KALYDECO tablets**

KALYDECO is supplied as oral granules for children with CF age 1 month to less than 6 years old

Meet Grant and learn how to take KALYDECO oral granules

View **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.

How KALYDECO oral granules are packaged

Not actual size.

Not actual size.

Not actual size.

Not actual size.

Not actual size.

Each box of KALYDECO oral granules contains 4 wallet cards for a total of 56 unit dose packets—or a 28-day supply of granules.

Each wallet card contains 14 doses. This is enough for a week based on dosing twice a day every 12 hours.

KALYDECO granules are available in 5 different strengths (5.8-mg, 13.4-mg, 25-mg, 50-mg, and 75-mg packets). Your loved one's doctor will prescribe the appropriate dose based on your loved one's weight.

KALYDECO oral granules recommended doses

If your child is:	And weighs:	The recommended dose is:
1 month to less than 2 months old	3 kg or more (~7 lb or more)	One 5.8-mg packet every 12 hours Total daily dose: 11.6 mg
2 months to less than 4 months old	3 kg or more (~7 lb or more)	One 13.4-mg packet every 12 hours Total daily dose: 26.8 mg
4 months to less than 6 months old	5 kg or more (~11 lb or more)	One 25-mg packet every 12 hours Total daily dose: 50 mg
6 months to less than 6 years old	5 kg to less than 7 kg (~11 lb to less than ~15 lb)	One 25-mg packet every 12 hours Total daily dose: 50 mg
	7 kg to less than 14 kg (~15 lb to less than ~31 lb)	One 50-mg packet every 12 hours Total daily dose: 100 mg
	14 kg or more (~31 lb or more)	One 75-mg packet every 12 hours Total daily dose: 150 mg

How often should my loved one take KALYDECO?

- Give your loved one KALYDECO every 12 hours with fat-containing food unless otherwise directed by your healthcare provider
- Your healthcare provider may give you different instructions on how much KALYDECO to give your loved one and when you should give it

How to give your loved one KALYDECO oral granules

Step 1: Preparation

- **Hold 1 packet of KALYDECO oral granules with the cut line on top**
- **Shake the packet gently to settle the KALYDECO granules**
- **Tear or cut the packet open along the cut line**
- Carefully pour all of the KALYDECO granules into 1 teaspoon (5 mL) of age-appropriate soft food or liquid and mix. Food or liquid should be at or below room temperature
- Here are examples of soft foods and liquids you can mix KALYDECO granules into. Remember, every child is different, so be sure to talk to your healthcare provider about what the best options are for your loved one

  - Breast milk
  - Applesauce
  - Infant formula
  - Water
  - Pureed vegetables and fruits
  - Milk
  - Yogurt
  - Juice

- Then, mix the granules with the 1 teaspoon of food or liquid

Step 2: Administration

- Give KALYDECO to your loved one within one hour of mixing
- Make sure the entire medicine mixture is taken

Step 3: Fat-containing food before or after the dose

Always give KALYDECO to your loved one with a fat-containing food

- Make sure to give your loved one age-appropriate fat-containing food just before or after the dose of KALYDECO granules. This helps the body absorb KALYDECO better
- **Here are suggestions for fat-containing foods to give your loved one:**

  - Breast milk
  - Infant formula
  - Eggs
  - Butter
  - Peanut butter
  - Cheese pizza
  - Whole milk
  - Whole-milk cheese
  - Whole-milk yogurt

- Talk to your healthcare provider about fat-containing foods appropriate for your loved one when taking KALYDECO oral granules.

What if your loved one misses a dose of KALYDECO?

If a dose of KALYDECO is missed and it is **within 6 hours** of when it is usually given, give that dose of KALYDECO as prescribed with fat-containing food as soon as possible.

If a dose of KALYDECO is missed and it is **more than 6 hours** after the time the dose is usually given, **skip that dose only** and give the next dose with fat-containing food when it is usually given. Do **not** give 2 doses at the same time to make up for a missed dose.

FAQs
Read the answers to questions you may have about KALYDECO.

Patient Stories With KALYDECO
Read stories from the KALYDECO community.

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For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

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How to take KALYDECO oral granules

How to take KALYDECO tablets

KALYDECO is supplied as tablets (150 mg) for people 6 years and older.

- Each KALYDECO box contains 4 individual blister cards. Each blister card contains 14 pills—7 morning doses and 7 evening doses

Not actual size.

How often should you take KALYDECO tablets?

- Take KALYDECO every 12 hours with fat-containing food unless otherwise directed by your healthcare provider
- Your healthcare provider may recommend a different dose or frequency for KALYDECO. Take KALYDECO exactly as your doctor tells you to take it

What if you miss a dose of KALYDECO?

If you miss a dose of KALYDECO and it is **within 6 hours** of when you usually take it, take the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

If you miss a dose and it is **more than 6 hours** after the time you usually take it, **skip that dose** only and take the next dose with fat-containing food when you usually take it. Do **not** take 2 doses at the same time to make up for a missed dose.

FAQs
Read the answers to questions you may have about KALYDECO.

Patient Stories With KALYDECO
Read stories from the KALYDECO community.

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KALYDECO can cause serious side effects, including:

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Fat-Containing Food Ideas

Looking for fat-containing food ideas?

Every dose of KALYDECO® must be taken with a meal or snack that contains fat to help your body absorb the medicine. You can get some delicious food ideas below. Remember to talk to your healthcare provider or dietitian before making any changes to your diet.

Easy ways to add fat to your foods	
Drizzle on extra-virgin olive oil	Spread on butter
Mix in sliced almonds	Mash in avocado

Morning meals	Evening meals
Oatmeal with whole milk, almonds, and fruit	Tater tot bake
Bagel with peanut butter	Pasta with meat sauce
Overnight oats with whole milk and blueberries	Macaroni and cheese
Whole-milk yogurt sweetened with sliced fresh fruit	Quesadilla with whole-milk cheese
Chocolate chip pancakes	Whole-milk cheese pizza

Quick snacks for when you're on the go	
Chocolate pudding	Multigrain toast with cream cheese and jelly
Whole-milk mozzarella string cheese	Strawberry whole-milk yogurt milkshake
Hard-boiled eggs	Peanut butter with celery

When taking KALYDECO, avoid foods and drinks that contain grapefruit as these may affect the amount of KALYDECO in the body.

These lists are not intended to be complete. Not all foods may be appropriate for children. Talk to your loved one's healthcare provider if you have questions about age-appropriate fat-containing food options.

Visit fdc.nal.usda.gov for foods and their fat content.

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Cooper
Age 4, L206W

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Every story is unique. KALYDECO brings them together.

"We were excited to get Cooper started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

1 / 5

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Brody got an early start with KALYDECO

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Makson
Age 7, R117H

For Kristen and Makson, sticking to a routine works

My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

Read More

Stacy
Age 33, G551D

Stacy is passionate about her music and her health

Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me.

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Carter
Age 21, G551D

Carter stays diligent about taking his KALYDECO

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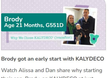

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Age 21 Months, G551D

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Stella

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Kaitlin finds strength in her support system

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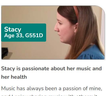

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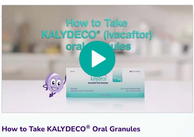

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How Does KALYDECO® Work?

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Resources

Stories | Videos | Downloadable Resources | FAQs

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—Brody's parents, Alissa and Dan

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Lily
Age 11, G551D

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"We're grateful for KALYDECO."
—Lily's mom, Carissa

3 / 5

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My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

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Age 27, G551D

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"It's so exciting and rewarding to be able to help spread awareness about CF!"

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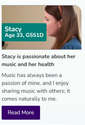

Stacy
Age 33, G551D

Stacy is passionate about her music and her health

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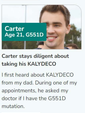

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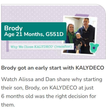

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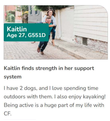

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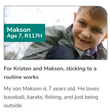

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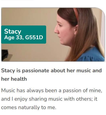

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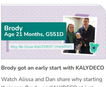

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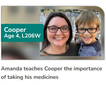

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What should I avoid while taking KALYDECO?

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- loss of appetite
- nausea or vomiting
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- headache
- upper respiratory tract infection (common cold), including:
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Resources

Stories | Videos | Downloadable Resources | FAQs

Cooper
Age 4, L206W

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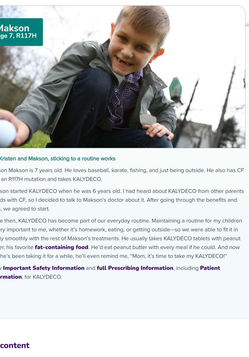
We were excited to get Cooper started and believed it would benefit him in the long run.
— Cooper's mom, Amanda

1 / 5

Hear from the KALYDECO community



Makson
Age 7, R117H

For Kristen and Makson, sticking to a routine works

My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside. He also has CF with an R117H mutation and takes KALYDECO.

Makson started KALYDECO when he was 6 years old. I had heard about KALYDECO from other parents of kids with CF, so I decided to talk to Makson's doctor about it. After going through the benefits and risks, we agreed to start.

Since then, KALYDECO has become part of our everyday routine. Maintaining a routine for my children is very important to me, whether it's homework, eating, or getting outside—so we were able to fit it in pretty smoothly with the rest of Makson's treatments. He usually takes KALYDECO tablets with peanut butter, his favorite **fat-containing food**. He'd eat peanut butter with every meal if he could. And now that he's been taking it for a while, he'll even remind me, "Mom, it's time to take my KALYDECO!"

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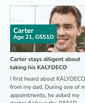

Stacy
Age 33, G551D

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Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me.

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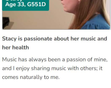

Brody
Age 2 months, G551D

Brody got an early start with KALYDECO

Watch Alissa and Dan share why starting their son, Brody, on KALYDECO at just 6 months old was the right decision for them.

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5441L

Mark strives to stay strong and active

I have enjoyed most of my life with my wife. I thrive on adventure. I enjoy being outdoors and being active. Life with CF has had its share of challenges.

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Age 27, G551D

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Age 11, G551D

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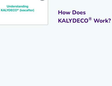

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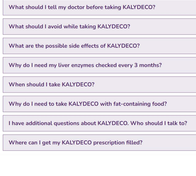

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Resources

Stories | Videos | Downloadable Resources | FAQs

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Age 4, L206W

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— Cooper's mom, Amanda

1 / 5

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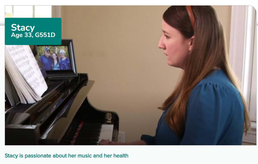

Stacy
Age 33, G551D

Watch Stacy's story

Stacy is passionate about her music and her health

Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me. I've known I wanted to be a music teacher since I was 9 years old.

I was diagnosed with cystic fibrosis when I was 6 years old; a genetic test showed I had the G551D mutation. I had to make adjustments to my diet and some of my activities, but I've tried to never let CF hold me back.

Managing CF can be complex, so it's really important to have a close relationship with your doctor. During one of my regular appointments with my CF healthcare team, I heard about KALYDECO. I was very interested and started asking my doctor a lot of questions.

My doctor felt it would be a good choice for me, because I have the G551D mutation. Before taking KALYDECO, my doctor and I discussed the possible side effects of KALYDECO, including that KALYDECO can cause serious side effects.

It's always been important to me to find ways to follow my passion for playing music, while making my health a priority. And that includes taking KALYDECO, along with my other prescribed CF treatments.

Stacy was sponsored by Vertex Pharmaceuticals Incorporated to share her story.

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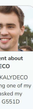

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Age 7, R117H

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My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

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Age 21, G551D

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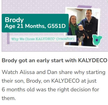

Brody
Age 21 Months, G551D

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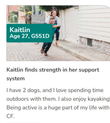

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Kaitlin finds strength in her support system

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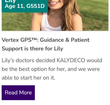

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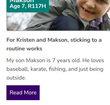

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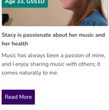

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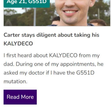

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Resources

Cooper
Age 4, L206W

People with CF pictured may or may not be taking KALYDECO.

Every story is unique. KALYDECO brings them together.

We were excited to get Cooper started and believed it would benefit him in the long run.
— Cooper's mom, Amanda

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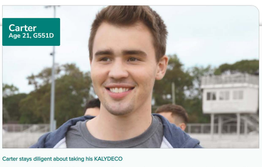
Hear from the KALYDECO community



Carter
Age 21, G551D

Carter stays diligent about taking his KALYDECO

I first heard about KALYDECO from my dad. During one of my appointments, he asked my doctor if I have the G551D mutation. My doctor checked and, sure enough, I did. I immediately got excited because of everything my doctor and my dad told me about KALYDECO. My doctor told me about potential side effects and, in the end, my dad and I felt comfortable moving forward with KALYDECO.

When I began taking KALYDECO, my mom helped me get organized and made sure I took it as my doctor had instructed. These days, I stay diligent about my routine and make sure I carve out time for my treatments.

Life with CF can sometimes be challenging, but I stay positive thanks to my relationships and knowing that my friends and family are always there for me.

View **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.

Maksan
Age 7, R117H

For Kristen and Maksan, sticking to a routine works

My son Maksan is 7 years old. He loves baseball, karate, fishing, and just being outside.

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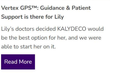

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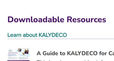

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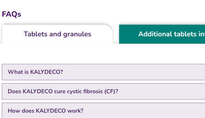

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How to Take KALYDECO® Oral Granules

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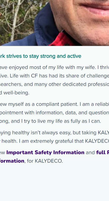

Mark
S945L

Mark strives to stay strong and active

I have enjoyed most of my life with my wife. I thrive on adventure. I enjoy being outdoors and being active. Life with CF has had its share of challenges. I have a lot to be thankful for—physicians, nurses, researchers, and many other dedicated professionals who have supported and monitored my health and well-being.

I view myself as a compliant patient. I am a reliable participant, a collaborator prepared for each doctor appointment with information, data, and questions to help manage my health. I always strive to stay strong, and I try to live my life as fully as I can.

Staying healthy isn't always easy, but taking KALYDECO helps me know that I am doing what I can for my health. I am extremely grateful that KALYDECO is here for me.

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Age 7, R117H

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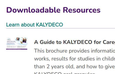

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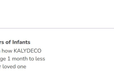

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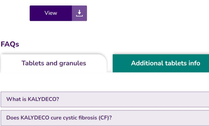

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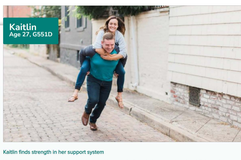

Kaitlin
Age 27, G551D

Kaitlin finds strength in her support system

I have 2 dogs, and I love spending time outdoors with them. I also enjoy kayaking! Being active is a huge part of my life with CF. My favorite kinds of exercise are running and hot yoga. They help my balance, strength, and mindset.

When I started taking KALYDECO, I noticed a change in my health. My weight increased and my pulmonary function tests improved. Seeing how KALYDECO has impacted my health is my motivation to continue taking it and to further participate in the CF community. It's so exciting and rewarding to be able to help spread awareness about CF!

I have a pretty amazing support system. My family and friends are nothing short of encouraging. I have been blessed to find a wonderful husband, and he and his family have been so supportive. They all push me to be my best!

KALYDECO fits into my daily routine. I work the night shift as a nurse, and I've found that setting an alarm on my phone really helps me step away from whatever I am doing to just grab a snack and take my medication. My favorite thing to take it with is a big spoonful of peanut butter and some nuts, cheese, and dried fruit. I'm so grateful for KALYDECO!

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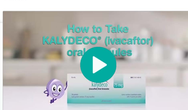

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Learn about KALYDECO

A Guide to KALYDECO for Caregivers of Infants
This brochure provides information on how KALYDECO works, results for studies in children age 1 month to less than 2 years old, and how to give your loved one KALYDECO oral granules.

View

Descargar Recurso en Español

Learn how to take KALYDECO

A Guide to KALYDECO (Tablets)
Instructions for people age 6 years and older on how to take KALYDECO tablets.

View

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
- Does KALYDECO cure cystic fibrosis (CF)?
- How does KALYDECO work?
- I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?
- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?
- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- ***Abnormality of the eye lens (cataract),*** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
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  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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Resources

Stories | Videos | Downloadable Resources | FAQs

Every story is unique. KALYDECO brings them together.

Cooper
Age 4, L206W

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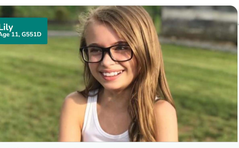
"We were excited to get Cooper started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

1 / 5

Hear from the KALYDECO community



Vertex GPS™: Guidance & Patient Support is there for Lily

Lily's doctors decided KALYDECO would be the best option for her, and we were able to start her on it. Within a week, we were able to notice changes in Lily. She is diligent about her treatment and sticks to her routine. Lily learned how to take pills in order to take KALYDECO. We're grateful for KALYDECO.

Vertex GPS™: Guidance & Patient Support has been beyond helpful during our KALYDECO journey. They are always there to help when we have questions about product or insurance support. It makes me feel good knowing they are here to help. Vertex seems to truly care, and that's a great feeling.

Lily's mom, Carissa

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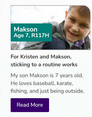

For Kristen and Makson, sticking to a routine works

My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

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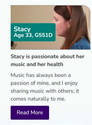

Stacy is passionate about her music and her health

Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me.

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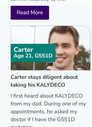

Carter stays diligent about taking his KALYDECO

I first heard about KALYDECO from my dad. During one of my appointments, he asked my doctor if I have the G551D mutation.

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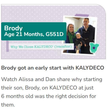

Brody got an early start with KALYDECO

Watch Alissa and Dan share why starting their son, Brody, on KALYDECO at just 6 months old was the right decision for them.

Watch

Mark strives to stay strong and active

I have enjoyed most of my life with my wife. I thrive on adventure. I enjoy being outdoors and being active. Life with CF has had its share of challenges.

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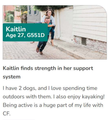

Kaitlin finds strength in her support system

I have 2 dogs, and I love spending time outdoors with them. I also enjoy kayaking! Being active is a huge part of my life with CF.

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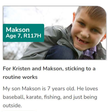

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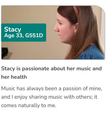

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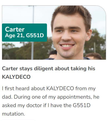

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Videos

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Resources

Stories | Videos | Downloadable Resources | FAQs

Cooper
Age 4, L206W

People with CF pictured may or may not be taking KALYDECO.

Every story is unique. KALYDECO brings them together.

"We were excited to get Cooper started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

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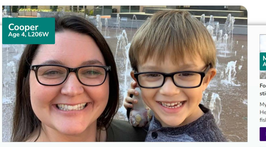
Hear from the KALYDECO community



Cooper
Age 4, L206W

Amanda teaches Cooper the importance of taking his medicines

Cooper loves doing tae kwon do. He's one of the youngest and smallest in his class, but he always gets out and does his best. His care team has mentioned that staying active has helped him stay healthy as he continues to grow!

When KALYDECO was approved for Cooper's gene mutation, we talked to his doctor about the benefits and risks of KALYDECO. We were excited to get him started and believed it would benefit him in the long run. We noticed improvements in sweat chloride levels within the first few weeks, even during the hot Texas summer!

We talk to Cooper every day about the importance of taking his medications and the long-term impact CF can have on his body. Cooper takes both his morning and evening doses with chocolate hazelnut spread, his favorite fat-containing food. Today, taking KALYDECO has become part of our regular routine.

Cooper's mom, Amanda

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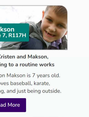

Makson
Age 7, R117H

For Kristen and Makson, sticking to a routine works

My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

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Stacy
Age 33, G551D

Stacy is passionate about her music and her health

Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me.

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Carter
Age 21, G551D

Carter stays diligent about taking his KALYDECO

I first heard about KALYDECO from my dad. During one of my appointments, he asked my doctor if I have the G551D mutation.

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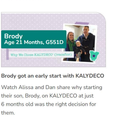
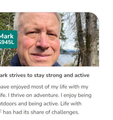


Brody
Age 23 Months, G551D

Brody got an early start with KALYDECO

Watch Alissa and Dan share why starting their son, Brody, on KALYDECO at just 6 months old was the right decision for them.

Watch

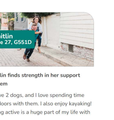


Mark
S945L

Mark strives to stay strong and active

I have enjoyed most of my life with my wife. I thrive on adventure. I enjoy being outdoors and being active. Life with CF has had its share of challenges.

Read More



Kaitlin
Age 27, G551D

Kaitlin finds strength in her support system

I have 2 dogs, and I love spending time outdoors with them. I also enjoy kayaking! Being active is a huge part of my life with CF.

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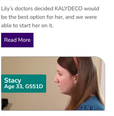

Lily
Age 11, G551D

Vertex GPS™: Guidance & Patient Support is there for Lily

Lily's doctors decided KALYDECO would be the best option for her, and we were able to start her on it.

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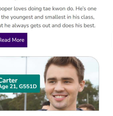

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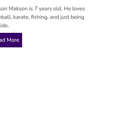

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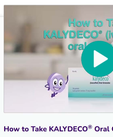

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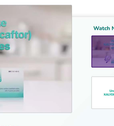

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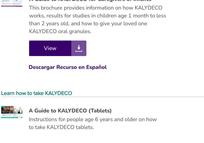

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Downloadable Resources

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A Guide to KALYDECO for Caregivers of Infants
This brochure provides information on how KALYDECO works, results for studies in children age 1 month to less than 2 years old, and how to give your loved one KALYDECO oral granules.

View

Descargar Recurso en Español

Learn how to take KALYDECO

A Guide to KALYDECO (Tablets)
Instructions for people age 6 years and older on how to take KALYDECO tablets.

View

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
- Does KALYDECO cure cystic fibrosis (CF)?
- How does KALYDECO work?
- I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?
- What should I tell my doctor before taking KALYDECO?
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- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked every 3 months?
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- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

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- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
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  - light-headedness or dizziness
- ***Abnormality of the eye lens (cataract),*** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

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For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

VERTEX

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Resources

Stories | Videos | Downloadable Resources | FAQs

Cooper
Age 4, L206W

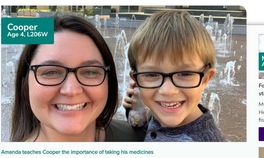
People with CF pictured may or may not be taking KALYDECO.

Every story is unique. KALYDECO brings them together.

"We were excited to get Cooper started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

1 / 5

Hear from the KALYDECO community



Cooper
Age 4, L206W

Amanda teaches Cooper the importance of taking his medicines

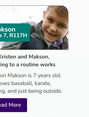
Cooper loves doing tae kwon do. He's one of the youngest and smallest in his class, but he always gets out and does his best. His care team has mentioned that staying active has helped him stay healthy as he continues to grow!

When KALYDECO was approved for Cooper's gene mutation, we talked to his doctor about the benefits and risks of KALYDECO. We were excited to get him started and believed it would benefit him in the long run. We noticed improvements in sweat chloride levels within the first few weeks, even during the hot Texas summer!

We talk to Cooper every day about the importance of taking his medications and the long-term impact CF can have on his body. Cooper takes both his morning and evening doses with chocolate hazelnut spread, his favorite fat-containing food. Today, taking KALYDECO has become part of our regular routine.

Cooper's mom, Amanda

View **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.



Makson
Age 7, R117H

For Kristen and Makson, sticking to a routine works

My son Makson is 7 years old. He loves baseball, karate, fishing, and just being outside.

Read More

Stacy
Age 33, G551D

Stacy is passionate about her music and her health

Music has always been a passion of mine, and I enjoy sharing music with others; it comes naturally to me.

Read More

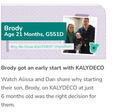
Carter
Age 21, G551D

Carter stays diligent about taking his KALYDECO

I first heard about KALYDECO from my dad. During one of my appointments, he asked my doctor if I have the G551D mutation.

Read More

All content



Brody
Age 23 Months, G551D

Why We Chose KALYDECO® (Ivacaftor)

Brody got an early start with KALYDECO

Watch Alissa and Dan share why starting their son, Brody, on KALYDECO at just 6 months old was the right decision for them.

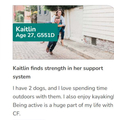
Watch

Mark
S945L

Mark strives to stay strong and active

I have enjoyed most of my life with my wife. I thrive on adventure. I enjoy being outdoors and being active. Life with CF has had its share of challenges.

Read More

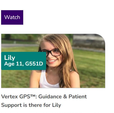


Kaitlin
Age 27, G551D

Kaitlin finds strength in her support system

I have 2 dogs, and I love spending time outdoors with them. I also enjoy kayaking! Being active is a huge part of my life with CF.

Read More



Lily
Age 11, G551D

Vertex GPS™: Guidance & Patient Support is there for Lily

Lily's doctors decided KALYDECO would be the best option for her, and we were able to start her on it.

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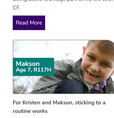

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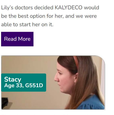

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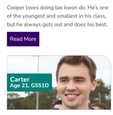

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Videos

Watch Next

How to Take KALYDECO® Oral Granules

How Does KALYDECO® Work?

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711+3A→G*	F311del	I148T	R75Q	S589N
2789+5G→A*	F311L	I175V	R117C*	S737F
3272-26A→G*	F508C	I807M	R117G	S945L*
3849+10kbC→T*	F508C; S1251N†	I1027T	R117H*	S977F*
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W*	R170H	S1251N*
A455E*	G178R*	L320V	R347H*	S1255P*
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q*	T1053I
D110H	G551D*	L1480P	R553Q	V232D
D192G	G551S*	M152V	R668C	V562I
D579G*	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H*	G1069R	P67L*	R1070Q	W1282R
D1270N	G1244E*	Q237E	R1070W*	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D*	Q359R	R1283M	
E822K	H939R	Q1291R	S549N*	
E831X*	H1375P	R74W	S549R*	

*Clinical data exists for these mutations. **See clinical studies**.

†Complex/compound mutations. Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

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  KALYDECO affects the CFTR protein "gating." KALYDECO helps the "gates" of the CFTR proteins stay open longer, allowing more chloride ions to move into and out of the cells. The movement of chloride ions may help keep a balance of salt and water in the lungs. KALYDECO does not increase the amount of CFTR proteins at the cell surface.

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- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?

  KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve.

  Avoid food or drink containing grapefruit while you are taking KALYDECO.
- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
- Does KALYDECO cure cystic fibrosis (CF)?
- How does KALYDECO work?
- I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?
- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
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- What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

High liver enzymes in the blood have happened in people receiving KALYDECO.

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
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- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?
- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?

  Take KALYDECO orally every 12 hours with fat-containing food unless otherwise directed by your healthcare provider.

  Please see full dosing information.
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
- Does KALYDECO cure cystic fibrosis (CF)?
- How does KALYDECO work?
- I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?
- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?
- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?

  KALYDECO should be taken with fat-containing food because fat-containing food helps the body absorb KALYDECO better.
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
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- Why do I need my liver enzymes checked every 3 months?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?

  If you have questions about KALYDECO, please talk to your doctor. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.
- Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- What is KALYDECO?
- Does KALYDECO cure cystic fibrosis (CF)?
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- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. Who should I talk to?
- Where can I get my KALYDECO prescription filled?

  Prescriptions for KALYDECO can only be filled at authorized specialty pharmacies. If you'd like to see a list of specialty pharmacies and specialty distributors, **click here**. Based on your health plan, there may be restrictions on which pharmacies you can use.

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

You may cut along the dotted line to separate your doses from the blister card.

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

KALYDECO should be stored at 68°F to 77°F (20°C to 25°C).

Do not use KALYDECO after the expiration date on the package.

Keep KALYDECO and all medicines out of the reach of children.

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

For people 6 years and older, KALYDECO tablets are supplied as light blue, film-coated, capsule-shaped tablets containing 150 mg of ivacaftor. Each tablet is printed with the characters "V 150" on one side and plain on the other.

Not actual size.

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

If you miss a dose of KALYDECO and it is **within 6 hours** of when you usually take it, take the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

If you miss a dose and it is **more than 6 hours** after the time you usually take it, **skip that dose only** and take the next dose with fat-containing food when you usually take it.

Do **not** take 2 doses at the same time to make up for a missed dose.

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- Can I separate the doses on the blister cards?
- How should I store KALYDECO tablets?
- What do KALYDECO tablets look like?
- What if I miss a dose of KALYDECO?
- I have additional questions about KALYDECO. Who should I talk to?

  If you have questions about KALYDECO, please talk to your healthcare provider. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

The granules should be taken within 1 hour of mixing with soft food or liquid. Make sure all medicine is taken.

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

KALYDECO should be stored at room temperature between 68°F to 77°F (20°C to 25°C).

Do not use KALYDECO after the expiration date on the package.

Keep KALYDECO and all medicines out of the reach of children.

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

KALYDECO is supplied as oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg packets) for people age 1 month to less than 6 years.

Not actual size.

Not actual size.

Not actual size.

Not actual size.

Not actual size.

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

The recommended dose of KALYDECO oral granules for children age 1 month to less than 6 years old is based on weight.

The recommended dose of KALYDECO oral granules for children age **1 month to less than 2 months old** who weigh **3 kg (~7 lb) or more** is one 5.8-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 11.6 mg.

The recommended dose of KALYDECO oral granules for children age **2 months to less than 4 months old** who weigh **3 kg (~7 lb) or more** is one 13.4-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 26.8 mg.

The recommended dose of KALYDECO oral granules for children age **4 months to less than 6 months old** who weigh **5 kg (~11 lb) or more** is one 25-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 50 mg.

Children who weigh **5 kg to less than 7 kg (~11 lb to less than ~15 lb)** should take one 25-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 50 mg.

Children who weigh **7 kg to less than 14 kg (~15 lb to less than ~31 lb)** should take one 50-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 100 mg.

Children who weigh **14 kg (~31 lb) or more** should take one 75-mg packet mixed with one teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 150 mg.

Give your loved one fat-containing food just before or just after the dose of KALYDECO granules. This helps the body absorb KALYDECO better.

Your healthcare provider may give you different instructions on how much KALYDECO to give your loved one and when you should give it.

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

  Yes, KALYDECO oral granules can be mixed with 1 teaspoon (5 mL) of breast milk or prepared infant formula at or below room temperature. Be sure that the entire mixture is taken by your loved one within 1 hour. Remember you should always give your loved one KALYDECO with a fat-containing food.
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?

  If your loved one misses a dose of KALYDECO and it is **within 6 hours** of when it is usually given, give the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

  If your loved one misses a dose and it is **more than 6 hours** after the time the dose is usually given, **skip that dose only** and give the next dose with fat-containing food when it is usually given.

  Do **not** give 2 doses at the same time to make up for a missed dose.
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

  Yes, you can mix KALYDECO granules with fat-containing food, for example, 1 teaspoon (5 mL) of whole-milk yogurt or milk, to give to your loved one. But your loved one should still eat fat-containing food just before or after taking the mixture.
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

  Yes, breast milk and prepared infant formula qualify as fat-containing food.
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

  The granules should be mixed with soft food or liquid at room temperature or below.
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
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- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?

  The entire contents of each packet should be mixed with 1 teaspoon (5 mL) of age-appropriate soft food or liquid. The mixture should be given within 1 hour of being mixed. Make sure all medicine is taken.
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?

  The granule formulation is sweetened but unflavored.
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
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- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?

  You should contact your loved one's healthcare provider to discuss this. Your pharmacist may also be a good resource.
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
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- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
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- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
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- How are KALYDECO oral granules packaged?
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- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- **If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?**

  You should give your loved one KALYDECO oral granules every 12 hours or as prescribed by your loved one's healthcare provider.
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
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- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

  No, granules should be kept in the foil packet until they are ready to be used.
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
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- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?

  The packets are child-resistant.
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
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  KALYDECO granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) are for use in children who are 1 month to less than 6 years of age, while KALYDECO tablets (150-mg) are for use in children age 6 years and older. You and your loved one's healthcare provider should discuss when to transition your loved one to KALYDECO tablets.
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
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- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
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- Do the granules have a taste?
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- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?

  Yes, your loved one will need a new prescription when they change to a new strength or dosage form.
- I have additional questions about KALYDECO. Who should I talk to?

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
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- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

  If you have questions about KALYDECO, please talk to your doctor. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.

Vertex GPS™ is here to help you get there

Wherever life with cystic fibrosis (CF) takes you, Vertex GPS™: Guidance & Patient Support is here to help. Vertex GPS offers personalized, one-on-one support to help you start and stay on track. Once you're enrolled, you'll be assigned a dedicated Support Specialist who will be with you every step of the way.

VERTEX GPS™ GUIDANCE & PATIENT SUPPORT

Here are just some of the ways your Support Specialist can help:

Get you started on treatment by verifying your coverage and out-of-pocket costs with your **insurance company**. They'll also connect with your **healthcare provider** to discuss any requirements or questions your insurance company may have while determining coverage.

Help you explore financial assistance options, regardless of your insurance coverage. And if you have commercial insurance, the Vertex GPS Co-pay Assistance Program may be able to lower your co-pay to as little as $0 per fill.*

*Eligibility restrictions and limitations apply. Annual assistance is limited to a maximum of $20,000.

Keep you on track with your treatment by coordinating shipments with your **specialty pharmacy** and reminding you when it's time to refill your Vertex medicine. And if your daily routine changes, they can help you pre-plan refills, ship your treatment to a new address, and share tips to help you stay motivated.

Not enrolled in Vertex GPS?

If you have been prescribed a Vertex treatment, ask your healthcare provider to complete an enrollment form for you.

Already enrolled?

If you are currently enrolled in GPS, you can call or text your Support Specialist at **1-877-752-5933 (press 2 when calling)**, Monday through Friday, from 8:30 AM to 7 PM ET.

Personalized support—for whatever's up next

Learn more about GPS and the support resources available at VertexGPS.com.

Discover more

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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Recursos en Español

Recursos Descargables

Descargue el folleto y las guías que se encuentran a continuación para obtener más información sobre KALYDECO.
Aquí encontrará información sobre cómo funciona KALYDECO, si usted o su ser querido son elegibles y cómo tomar los comprimidos y los gránulos.

Obtenga información sobre KALYDECO

Una guía sobre KALYDECO para cuidadores de bebés

Este folleto ofrece información sobre cómo funciona KALYDECO, los resultados de los estudios realizados en niños de entre 1 mes y menos de 2 años de edad y cómo darle a su ser querido gránulos orales de KALYDECO.

Ver

¿Son elegibles usted o su ser querido para el tratamiento con KALYDECO?

Esta guía ofrece una forma rápida y fácil de comprobar su elegibilidad o la de su ser querido.

Ver

Aprenda cómo tomar KALYDECO

Una guía sobre KALYDECO (comprimidos)

Instrucciones sobre cómo tomar comprimidos KALYDECO para personas de 6 años o más.

Ver

IMPORTANT SAFETY INFORMATION

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- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
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For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
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Important Safety Information & Indication

IMPORTANT SAFETY INFORMATION

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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
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  - before you start KALYDECO
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You may be able to find what you're looking for on the KALYDECO® home page.

Back to home

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Site Map

Home

About KALYDECO
- How KALYDECO Works
- Who KALYDECO Is For
- KALYDECO Results

Safety & Side Effects
- Safety & Side Effects

Taking KALYDECO
- How to Take KALYDECO
- Fat-Containing Food Ideas

Resources
- Stories, Videos, and Downloads
- FAQs
- Vertex GPS™: Patient Support Program
- Recursos En Español

Important Safety Information
- Important Safety Information

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This site is intended for US healthcare professionals.

Are you a US healthcare professional?

Yes No

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kalydeco (ivacaftor) tablets 150 mg, oral granules 5.8•13.4•25•50•75 mg

MENU

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Home

About KALYDECO

How KALYDECO Works

Who KALYDECO Is For

KALYDECO Results

Safety & Side Effects

Taking KALYDECO

Resources

Vertex GPS™: Guidance & Patient Support

For Healthcare Professionals

Ficha Técnica

Información para el Paciente

kalydeco (ivacaftor) tablets 150 mg oral granules 5.8•13.4•25•50•75 mg

Home

About KALYDECO

Safety & Side Effects

Taking KALYDECO

How to Take KALYDECO

Fat-Containing Food Ideas

Resources

Vertex GPS™: Guidance & Patient Support

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About KALYDECO

Safety & Side Effects

Taking KALYDECO

Resources

Stories, Videos, and Downloads

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Recursos En Español

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People with CF pictured thus far play out for on KALYDECO.

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Mutation 1

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Mutation 2 (if known)

Submit

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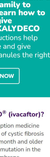

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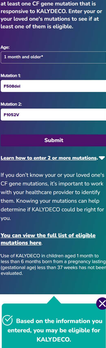

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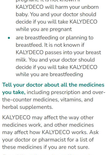

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Serious allergic reactions have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:

- rash or hives
- tightness of the chest or throat or difficulty breathing
- light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

People with CF pictured may or may not be taking KALYDECO.

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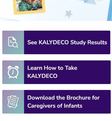
Treating the underlying cause is another first worth remembering.

Talk to your healthcare provider to see if KALYDECO is right for you or your loved one.

People with CF genotypes other than those listed may not be on KALYDECO.



See KALYDECO Study Results

Learn How to Take KALYDECO

Download the Brochure for Caregivers of Infants

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) aged 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible.

Age:

1 month and older*

Mutation 1:

F508del

Mutation 2:

F508del

Submit

Learn how to enter 2 or more mutations

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

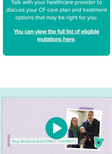
You can view the full list of eligible mutations here

*KALYDECO is indicated in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Neither CF gene mutation you entered is eligible for KALYDECO.

Talk with your healthcare provider to discuss your CF care plan and treatment options that may be right for you.

You can view the full list of eligible mutations here



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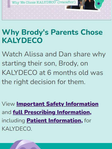

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KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (ZALANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
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  - runny nose
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- diarrhea
- rash
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For further information, please see **full Prescribing Information**, including **Patient Information**.

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Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) ages 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible.

Age:
1 month and older*

Mutation 1:
test

Mutation 2:
Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

You can view the full list of eligible mutations here

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We're sorry, we do not recognize 1 or both of the mutations you entered.

Talk to your healthcare provider to discuss your CF gene plan. They can help determine what treatment option is right for you at this time.

You can view the full list of eligible KALYDECO mutations here

Why We Chose KALYDECO

Why Brody's Parents Chose KALYDECO

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Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

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Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
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What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
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KALYDECO (ivacaftor) tablets

MENU

Treating the underlying cause is another first worth remembering.

Talk to your healthcare provider to see if KALYDECO is right for you or your loved one.

People with CF aged 2 years and older may not be on KALYDECO.

See KALYDECO Study Results

Learn How to Take KALYDECO

Download the Brochure for Caregivers of Infants

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) ages 2 months and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if it could be an option for you.

Age:

1 month and older*

Mutation 1

Mutation 1

Mutation 2:

Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations

Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

To enter 2 or more mutations into 1 entry field, separate them with a semicolon, space, comma, or forward slash. For example, if your mutations are R74W/V201M/D110H and W1282X, use the Mutation 1 field to enter: R74W; V201M; D110H; and the Mutation 2 field to enter: W1282X.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

You can view the full list of eligible mutations here

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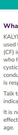

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Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of those medicines if you are unsure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFADIN®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROL®), or phenytoin (DILANTIN®, PHENYTEK®)
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What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

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  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

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- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
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- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
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  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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kalydeco® (ivacaftor) tablets

How KALYDECO® Works

The underlying cause of cystic fibrosis (CF)

CF is caused by cystic fibrosis transmembrane conductance regulator (CFTR) protein defects. A mutation in the genes of a person with CF may make defective CFTR proteins that:

- Don't open correctly
- Don't get to the cell surface, where they are normally located

A person with CF may make CFTR proteins that have either or both of these defects.

Because of these defects, chloride ions cannot flow freely into or out of the cells as they should, leading to an imbalance of salt and water. This can lead to thick, sticky mucus in the lungs.

See how KALYDECO works

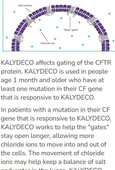
Watch This Video to See How KALYDECO Works

Learn how KALYDECO helps certain CFTR proteins work better.

View **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.

KALYDECO targets the underlying cause

CFTR proteins with KALYDECO



KALYDECO affects gating of the CFTR protein. KALYDECO is used in people age 1 month and older who have at least one mutation in their CF gene that is responsive to KALYDECO.

In patients with a mutation in their CF gene that is responsive to KALYDECO, KALYDECO works to help the "gates" stay open longer, allowing more chloride ions to move in and out of the cells. The movement of chloride ions may help keep a balance of salt and water in the cells. KALYDECO does not increase the number of CFTR proteins at the cell surface.

What is known about how KALYDECO works was learned from studies conducted in a lab. Keep in mind that results from laboratory studies do not always match how these medicines work in a person. If you have any questions about your KALYDECO treatment, please speak with your healthcare provider.

Patient Stories With KALYDECO
Read stories from the KALYDECO community.

Explore Resources
Brochures and tools to help you learn more about KALYDECO.

What is KALYDECO® (ivacaftor)?

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- nausea
- dizziness

Tell your doctor if you have any side effects that bother you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You can report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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kalydeco® (ivacaftor) tablets

MENU

Who KALYDECO® is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age:

1 month and older*

Mutation 1:

Mutation 1

Mutation 2:

Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients aged 1 month to less than 6 months born from a pregnancy testing (gestational age) less than 37 weeks has not been evaluated.

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. Currently KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

How KALYDECO Works
Learn how KALYDECO helps certain CFTR proteins work better

KALYDECO Clinical Studies
Review the results

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **Full Prescribing Information**, including **Patient Information**.

People with CF injured may or may not be taking KALYDECO.

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Who KALYDECO® Is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age:

1 month and older*

Mutation 1

F508del

Mutation 2

F508del

Submit

Learn how to enter 2 or more mutations.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Based on the information you entered, you may be eligible for KALYDECO.

Talk with your healthcare provider to see if KALYDECO is right for you.

Here is some information about KALYDECO that may be helpful.

See the Clinical Study Results

Learn About Safety and Side Effects

Watch How KALYDECO Works

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machinery until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood**, which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdomen) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information** including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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kalydeco (ivacaftor) tablets

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Who KALYDECO® Is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age:

1 month and older*

Mutation 1:

test

Mutation 2:

Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations

If you don't know your or your loved one's CF gene mutation, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients aged 1 month to less than 4 months and in women in pregnancy testing (gestational age) less than 37 weeks has not been evaluated.

We're sorry, we do not recognize 1 or both of the mutations you entered.

Talk to your healthcare provider to discuss your CF care plan. They can help determine what treatment option is right for you at this time.

You can view the full list of eligible KALYDECO mutations here.

View Eligible Mutations

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

How KALYDECO Works
Learn how KALYDECO helps certain CFTR proteins work better.

KALYDECO Clinical Studies
Review the results.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROL®) or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machinery until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF injured may or may not be taking KALYDECO.

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Who KALYDECO® Is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) age 1 month and older with at least one CF gene mutation that is responsive to KALYDECO. Enter your or your loved one's mutations to see if at least one of them is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age

1 month and older*

Mutation 1

Mutation 1

Mutation 2:

Mutation 2 (if known)

Submit

Learn how to enter 2 or more mutations

Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

To enter 2 or more mutations into 1 entry field, separate them with a semicolon, not a comma, or forward slash. For example, if your mutations are R74W/V201M/D110H and W1282X, use the Mutation 1 field to enter: R74W;V201M;D110H and the Mutation 2 field to enter: W1282X.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients aged 1 month to less than 6 months born from a pancreatic testing (gestational age) less than 37 weeks has not been evaluated.

If you don't know your or your loved one's CF gene mutations, it's important to work with your healthcare provider to identify them. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients aged 1 month to less than 6 months born from a pancreatic testing (gestational age) less than 37 weeks has not been evaluated.

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people age 1 month and older who have one of the following 97 CF gene mutations. If you don't see your mutation in this chart, try using the tool above or talk to your healthcare provider.

View Eligible Mutations

Talk to your doctor to learn if you have an indicated CF gene mutation

It is not known if KALYDECO is safe and effective in children under 1 month of age.

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of the 97 indicated mutations listed above.

How KALYDECO Works
Learn how KALYDECO helps certain CFTR proteins work better.

KALYDECO Clinical Studies
Review the results.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROL®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
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- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

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  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
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The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Who KALYDECO® is For

Check Your Eligibility

KALYDECO is for people with cystic fibrosis (CF) ages 1 month and older who at least one CF gene mutation that responds to KALYDECO. Talk to your your loved one's mutations to see if at least one of these is eligible. You can also use the chart below to determine if you are eligible for KALYDECO.

Age:

1 month and older*

Mutation 1

Mutation 1:

Mutation 2

Mutation 2 (if known):

Submit

Learn how to enter 2 or more mutations.

Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. If you know your mutations, 2 copies of the CF gene can be entered into the tool to see if KALYDECO may be an option.

To enter 2 or more mutations into 1 entry field, separate mutations with a comma, space, or semicolon. For example, if your mutations are F508del and G551D, you can enter 3CFTR1, 3CFTR2, F508del, G551D, R74W, V201M, D110H, and the Mutation 2 field is now not required.

If you don't know your or your loved one's CF gene mutations, it's important to talk to your doctor about testing for these genes. Knowing your mutations can help determine if KALYDECO could be right for you.

*Use of KALYDECO in patients ages 1 month to less than 6 months is based on efficacy in a clinical trial in patients ages less than 37 weeks has not been evaluated.

See which mutations KALYDECO is indicated for

KALYDECO is for the treatment of CF in people ages 1 month and older who have one of the following CF gene mutations. If you don't see your mutation in this chart, by using the tool above or talk to your healthcare provider.

711+3A→G[1]	F311del	I148T
2789+5G→A[1]	F311L	I175V
3272-26A→G[1]	F508C	I807M
3849+10kbC→T[1]	F508C,S1251N	I1027T
1717-1G→A[1]	F508del	I1139V
A234D	F1074L	K1060T
A349V	G178E	L206W[2]
A455E[1]	G178R[1]	L320V
A1067T	G194R	L967S
D110E	G314E	L997F
D110H	G551D*	L1480P
D1152-2A→G	G551S*	M152V
D1270N	G576A	M952I
E56K	G622R	Q237H
E193K	G1349D*	Q359R
D192G	G551S*	R117C*
E831X	H1375P	R74W
E92K	H939R	R117H*
F87S	R117G	S945L*
F311L	R117H*	S977F*
F508del	R117L	R117P
G85E	R117P	R117Q
G91R	R117Q	R334W
G970R	R117R	R347H
G1244E	R117W	R352Q*
G1349D	R334W	S549N*
G1349V	R347H	S549R
G1349R	R347P	S549R*
H609R	R352Q*	S1251N*
I148T	R352R*	S1255P
I336K	R352W	T338I
I507del	R553Q*	V232D
I507V	R560T	V562I
I1027T	R668C	V754M
I1139V	R709Q	V1293G
K1060T	R1070Q	W1282R
L206W	R1162X	W1282X
L320V	R1283M	Y1014C
L967S	R1283R	Y1032C
L997F	R1283S	Y1032R
M952I	R1283T	Y1092C
N1303K	R1283W	Y1092X
P67L	R1347P	Y1093H
P99T	R1347R	Y1093R
P205S	R1347S	Y1093S
P574H	R1453W	Y1093X
P1290L	R1453X	Y1095C
Q98R	R1517G	Y1095X
Q98X	R1517I	Y1098C
Q237E	R1517K	Y1098H
Q237H	R1517M	Y1098S
Q359R	R1517R	Y1098X
Q493R	R1517S	Y1099C
Q1291H	R1517T	Y1099H
R74W	R1517X	Y1099S
R117C*	R1522K	Y1099X
R117H*	R1522S	Y1109C
R117L	R1522T	Y1109H
R117P	R1522X	Y1109S
R117Q	R1549X	Y1109X
R117R	R1562X	Y1122C
R117W	R1626X	Y1122H
R334W	R1628X	Y1122S
R347H	R1653X	Y1122X
R347P	R1656H	Y1123C
R352Q*	R1658X	Y1123H
R352R*	R1662X	Y1123S
R352W	R1702H	Y1123X
R553Q*	R1747W	Y1125C
R560T	R1770W	Y1125H
R668C	R2143X	Y1125S
R709Q	R2421X	Y1125X
R1070Q	R2496X	Y1126C
R1162X	R2497X	Y1126H
R1283M	R2558X	Y1126S
R1283R	R2559X	Y1126X
R1283S	R2561X	Y1127C
R1283T	R2562X	Y1127H
R1283W	R2564X	Y1127S
R1347P	R2565X	Y1127X
R1347R	R2566X	Y1128C
R1347S	R2567X	Y1128H
R1453W	R2568X	Y1128S
R1453X	R2569X	Y1128X
R1517G	R2570X	Y1129C
R1517I	R2571X	Y1129H
R1517K	R2572X	Y1129S
R1517M	R2573X	Y1129X
R1517R	R2575X	Y1130C
R1517S	R2576X	Y1130H
R1517T	R2578X	Y1130S
R1517X	R2580X	Y1130X
R1522K	R2581X	Y1131C
R1522S	R2582X	Y1131H
R1522T	R2583X	Y1131S
R1522X	R2584X	Y1131X
R1549X	R2585X	Y1132C
R1562X	R2586X	Y1132H
R1626X	R2587X	Y1132S
R1628X	R2588X	Y1132X
R1653X	R2589X	Y1134C
R1656H	R2590X	Y1134H
R1658X	R2591X	Y1134S
R1662X	R2592X	Y1134X
R1702H	R2593X	Y1135C
R1747W	R2594X	Y1135H
R1770W	R2595X	Y1135S
R2143X	R2596X	Y1135X
R2421X	R2597X	Y1136C
R2496X	R2598X	Y1136H
R2497X	R2599X	Y1136S
R2558X	R2600X	Y1136X
R2559X	R2601X	Y1137C
R2561X	R2602X	Y1137H
R2562X	R2603X	Y1137S
R2564X	R2604X	Y1137X
R2565X	R2605X	Y1138C
R2566X	R2606X	Y1138H
R2567X	R2607X	Y1138S
R2568X	R2608X	Y1138X
R2569X	R2609X	Y1139C
R2570X	R2610X	Y1139H
R2571X	R2611X	Y1139S
R2572X	R2612X	Y1139X
R2573X	R2613X	Y1140C
R2575X	R2614X	Y1140H
R2576X	R2615X	Y1140S
R2578X	R2616X	Y1140X
R2580X	R2617X	Y1141C
R2581X	R2618X	Y1141H
R2582X	R2619X	Y1141S
R2583X	R2620X	Y1141X
R2584X	R2621X	Y1142C
R2585X	R2622X	Y1142H
R2586X	R2623X	Y1142S
R2587X	R2624X	Y1142X
R2588X	R2625X	Y1143C
R2589X	R2626X	Y1143H
R2590X	R2627X	Y1143S
R2591X

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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

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- St. John's wort
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What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

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Age 1 month to less than 4 months old

Study B

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

What is KALYDECO® (ivacaftor)?

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Especially tell your doctor if you take:

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- St. John's wort
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What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

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  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

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  - light-headedness or dizziness
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The most common side effects of KALYDECO include:

- headache
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  - runny nose
- stomach (abdominal) pain
- diarrhea
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Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Study 8

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

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Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medications such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of **97 indicated mutations**.

Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Study 6

G551D, S549N

Age 6 years and older

Age 12 years and older

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of **97 indicated mutations**.

Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Study 2 (age 6 through 11)

G551D

Study 4 (age 6 years and older)

G1244E, G1349D, G178R, G551S, G970R,* S1251N, S1255P, S549N, S549R

*KALYDECO is not indicated for people with cystic fibrosis (CF) who have the G970R mutation.

Study 5 (age 6 years and older)

R117H

Age 12 years and older

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF placed may or may not be taking KALYDECO.

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KALYDECO® Results

Keep in mind that not all mutations were evaluated in clinical studies, and those that were evaluated were not studied in all age groups. However, KALYDECO is approved for people age 1 month and older with any of **97 indicated mutations**.

Age 1 month to less than 4 months old

Age 4 months to less than 6 months old

Age 6 months to less than 1 year old

Age 1 to less than 2 years old

Age 2 to less than 6 years old

Age 6 years and older

Age 12 years and older

Study 1

G551D

Study 7

2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, A455E, D1152H, D579G, 2183X, L206W, P67L, R1070W, R117C, R347H, R352Q, S945L, S977F

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Back to all studies

Age 1 month to less than 4 months old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 7 children age 1 month to less than 4 months old.

See the results for children age 4 months to less than 6 months old

Mutations eligible to enroll in this part of the study were:

Any mutation responsive to KALYDECO.

Mutations included in this part of the study:

4 children had the G551D mutation. The 3 remaining children had R117C, R117H, and S945L mutations.

How KALYDECO was given

Children age 1 through 2 months old who weighed **3 kg (~7 lb) to less than 5 kg (~11 lb) received 5.7 mg of KALYDECO oral granules every 12 hours.**

Children age 2 through 3 months old who weighed **5 kg (~11 lb) or more** received **11.4 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food.

When they turned 4 months old, their dose was adjusted, if needed, based on weight.

Learn how to give your loved one KALYDECO oral granules

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information

Other study results

Sweat chloride

For children age 1 month to less than 4 months old who took KALYDECO: Sweat chloride decreased on average by -40.3 mmol/L through Week 24.

(average mmol/L beginning of study was 73.8)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV$_1$).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

FEV$_1$=forced expiratory volume, or how much air a person can exhale in a forced breath 1 second.

Study limitations

KALYDECO was approved in people age 1 month to less than 4 months old based on the efficacy shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top ^

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
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What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information** including **Patient Information**

People with CF potential may or may not be taking KALYDECO.

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KALYDECO® Results

Back to all studies

Age 4 months to less than 6 months old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study take KALYDECO.

One part of the study evaluated 6 children age 4 months to less than 6 months old.

See the results for children age 6 months to less than 1 year old

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study were:

5 children had the G551D mutation, and 1 had the R117H mutation.

How KALYDECO was given

All children weighed between **5 kg (~11 lb) and 7 kg (~15 lb)** and received **25 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments. When they turned 6 months old, their dose was adjusted, if needed, based on weight.

Learn how to give your loved one KALYDECO oral granules

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information

Other study results

Sweat chloride

For children age 4 months to less than 6 months old who took KALYDECO: Sweat chloride decreased on average by -50.0 mmol/L at Week 24.

(average mmol/L beginning of study visit 97.4)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV$_1$).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

FEV$_1$=forced expiratory volume, 1 hour much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 4 months to less than 6 months old based on the efficacy shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top ^

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

KALYDECO can cause dizziness in some people and may affect how you experience dizziness, do not drive or operate machines until symptoms improve

- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information** including **Patient Information**.

People with CF injured may or may not be taking KALYDECO.

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ivacaftor (KALYDECO®)

KALYDECO® Results

Back to all studies

Age 6 months to less than 1 year old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 11 children age **6 months to less than 1 year old**.

See the results for children age 1 year to less than 2 years old

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study:

10 children had the G551D mutation, and 1 had the G178R mutation.

How KALYDECO was given

Children who weighed **7 kg (~15 lb) to less than 14 kg (~31 lb)** received **50 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information

Other study results

Sweat chloride

For children age 6 months to less than 1 year old who took KALYDECO: Sweat chloride decreased on average by -58.6 mmol/L at Week 24.

(average mmol/L beginning of study was 101.5)

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV$_1$%).**

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO. "FEV$_1$-forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 6 months to less than 1 year old based on the efficacy shown in studies of KALYDECO in people age 2 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top ^

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROI®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

Should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. You should do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver disease:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection, including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Back to all studies

Age 1 to less than 2 years old

Study 8

The safety and tolerability of KALYDECO were evaluated in 43 children age 1 month to less than 2 years old with cystic fibrosis (CF). All the children in this study took KALYDECO.

One part of the study evaluated 19 children **age 1 to less than 2 years old.**

See the results for children age 6 months to less than 1 year old

Mutations eligible to enroll in this part of the study were:

G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R.

Mutations included in this part of the study:

16 had the G551D mutation, 2 had the S549R mutation, and 1 had the G178R mutation.

How KALYDECO was given

Children who weighed **7 kg (~15 lb) to less than 14 kg (~31 lb) received 50 mg of KALYDECO oral granules every 12 hours.**

Children who weighed **14 kg (~31 lb) to less than 25 kg (~55 lb) received 75 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed into 1 teaspoon of an age-appropriate soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules

Study results

Safety

The safety of KALYDECO, observed in this study, was similar to what was observed in KALYDECO studies in people with CF age 2 years and older.

See additional safety information

Other study results

Sweat chloride

For children age 1 year to less than 2 years old who took KALYDECO:

Sweat chloride decreased on average by −73.5 mmol/L at Week 24.

(average mmol/L beginning of study was 104.1)

Sweat chloride is a measure of the amount of salt in a person's sweat. A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV$_1$*).

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

*FEV$_1$=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 1 to less than 2 years old based on the benefits shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top ^

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO in clinical trials. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver enzymes.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

- **Serious allergic reactions** have happened in people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You can report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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kalydeco® (ivacaftor) tablets

KALYDECO® Results

Back to all studies

Age 2 to less than 6 years old

Study 6

Study 6 was a 24-week study in which the safety of KALYDECO was evaluated in 34 children **age 2 to less than 6 years old** with cystic fibrosis (CF). All children in this study took KALYDECO. No one in this study took placebo. The primary purpose of this study was to determine the safety and tolerability of KALYDECO.

Mutations eligible to enroll in this study were:

G551D, G1244V, G178R, G551D, G551S, G970R,* S1251N, S1255P, S549N, S549R.

*KALYDECO is not indicated for people with CF who have the G970R mutation.

Mutations included in this study:

32 children had the G551D mutation and 2 had the S549N mutation.

How KALYDECO was given

Children who weighed **less than 14 kg (~31 lb)** received **50 mg of KALYDECO oral granules every 12 hours.**

Children who weighed **14 kg (~31 lb) or more received 75 mg of KALYDECO oral granules every 12 hours.**

All children took KALYDECO oral granules mixed with 1 teaspoon of soft food or liquid every 12 hours with fat-containing food. All children continued to take their other CF treatments.

Learn how to give your loved one KALYDECO oral granules.

Study results

Safety

The type and frequency of side effects for children in the study were similar to those seen in KALYDECO studies with people with CF age 6 years and older.

High liver enzymes were more common in children who had abnormal liver enzymes before starting KALYDECO.

See additional safety information

Other study results

Sweat chloride

After taking KALYDECO: Sweat chloride decreased on average by −49 mmol/L through Week 24.

Sweat chloride is a measure of the amount of salt in a person's sweat. A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV_1%).

Because no one in this study took placebo, it is not known if changes in sweat chloride were due to KALYDECO.

FEV_1=forced expiratory volume, or how much air a person can exhale in a forced breath in 1 second.

Study limitations

KALYDECO was approved in people age 2 years to less than 6 years old based on the benefits shown in studies of KALYDECO in people age 6 years and older, as well as the safety assessment in this study.

Talk to your healthcare provider to learn more about how KALYDECO was approved in this age group.

Back to top ^

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people ages 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients.
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (ETQUEBX®, CARBATROL®, EQUETROL®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, fluconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (PEDIAZOLE®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people with CF. If you experience dizziness, do not drive or operate machinery until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold) including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 4 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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KALYDECO® Results

Back to study details

Age 6 years and older

Study 2

Study 2 was a 48-week open-label study in 246 people ages 6 years and older with CF who had at least one G551D mutation. KALYDECO (150 mg tablets) or ivacaftor-naïve subjects received KALYDECO for 48 weeks measured at different time points, including 24 and 48 weeks. All participants had a FEV1 of 40 to 103 percent predicted at the screening visit before taking the study drug. The study's primary endpoint was the absolute change from baseline in percent predicted FEV1 of respiratory symptoms, weight, and sweat chloride at 24 weeks compared to placebo.

FEV1=forced expiratory volume, or how much air a person can exhale in one second

Mutation eligibility to enroll and included in this study was:

- G551D

Other study results

CF respiratory symptoms

Long function (FEV1)

Long function increased 13.7 percentage points greater average improvement, compared to placebo, in absolute percent predicted FEV1 at 24 weeks. Long function can be measured with an FEV1, how much air a person can exhale in a forced breath (1 second).

Weight

Weight increased

About 2.8 kg (~6.16 lb) greater average weight increase at 24 weeks.

Sweat chloride

Sweat chloride decreased

After taking KALYDECO, sweat chloride decreased on average by 53 mmol/L, compared to placebo at 24 weeks.

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride is a sign that the medicine will be an improvement in lung function (FEV1).**

KALYDECO has also been studied in people ages 6 years and older with CF who had R117H or G551D mutations. Be sure to review the **Important Safety Information** and the **Important Information for People with CF** below **and** visit **KALYDECO.COM** for more information.

Important considerations

- Results for the mutations R117H and G551D are different. **Not all mutations showed the same level of benefit when taking KALYDECO.**
- Some people experienced less improvement compared to the average results for the people in the study. Others experienced more improvement than average.
- Talk to your healthcare provider to learn more about your specific mutation.

Study results

Long function (FEV1)

Long function increased

In the overall population for the 5 mutations studied, KALYDECO increased lung function by 10.7 percentage points average improvement in absolute percent predicted FEV1 compared to placebo at 24 weeks.

Results varied by mutation.

BHI is a measure of respiratory symptoms such as cough, shortness of breath, wheezing, for example, for a 6-yr-old, 1.55 is a little bit of trouble breathing, 3 is a lot of trouble breathing, and 4.5 is the most trouble breathing.

Results varied by mutation.

Respiratory symptoms are measured using the Bronchiectasis Health Index (BHI), which is a tool used to measure respiratory symptoms, including cough, sputum, and difficulty breathing.

BHI increased

In the overall population for the 5 mutations studied, KALYDECO increased the average increase in BHI by 4.7 points, compared to placebo at 24 weeks.

Results varied by mutation.

BHI is a measure of respiratory symptoms such as cough, shortness of breath, wheezing, for example, for a 6-yr-old, 1.55 is a little bit of trouble breathing, 3 is a lot of trouble breathing, and 4.5 is the most trouble breathing.

Results varied by mutation.

Sweat chloride

Sweat chloride decreased

In the overall population for the 5 mutations studied, KALYDECO decreased sweat chloride by 49.1 mmol/L. **A decrease in sweat chloride is a sign that the medicine will be an improvement in lung function (FEV1).**

Results varied by mutation.

Other mutations studied

CF respiratory symptoms

Long function (FEV1)

Long function can be measured with an FEV1, how much air a person can exhale in a forced breath (1 second).

Sweat chloride

Sweat chloride decreased

Sweat chloride is a measure of the amount of salt in your sweat. **A decrease in sweat chloride is a sign that the medicine will be an improvement in lung function (FEV1).**

Body mass index (BMI)

BMI is a measure of nutrition status in people ages 6 years and older. Yes, and your doctor should monitor your nutrition status.

Safety

Safety includes the most common side effects that occur during the study.

CF respiratory symptoms

Respiratory symptoms are measured by the FEV1 respiratory exterior gas, the Bronchiectasis Health Index (BHI) measure respiratory symptoms, including difficulty breathing.

Pulmonary exacerbations

Pulmonary exacerbations are a sudden worsening of respiratory symptoms, changes in the use of IV, IM, or oral antibiotics, and hospitalization.

Some people in this study showed improvement in these measures, but not all.

- Please talk to your healthcare provider if you'd like to learn about the results of this study.

Back to top ^

What is KALYDECO? (ivacaftor)®

KALYDECO is a prescription medicine for people ages 6 years and older with CF who have at least one mutation in the CFTR gene that is responsive to KALYDECO. It is not known if KALYDECO is responsive to KALYDECO.

KALYDECO may not be right for you if you have an individual CF gene mutation.

KALYDECO is not for people with CF who are not taken under 6 months of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your healthcare provider if you have:

- liver disease or cirrhosis
- have had a liver transplant or have been told by your doctor that you are candidate for a liver transplant. Patient Information for a list of contraindications.
- are pregnant or plan to become pregnant. It is unknown if KALYDECO will harm your unborn baby. You and your doctor should decide if KALYDECO is right for you during pregnancy.
- are breastfeeding or planning to breastfeed. It is unknown if KALYDECO passes into breast milk. You and your doctor should decide if KALYDECO is right for you while breastfeeding.

Tell your doctor about all the medicines you take. Some medicines may affect how KALYDECO works. Some other medicines may cause liver harm when taken with KALYDECO.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of those medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFADIN®, RIMACTANE®, RIFAMPIN SANDOZ®)
- tetrazepam (MUSCOFLEX®)
- the antifungals ketoconazole (NIZORAL®), itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®)
- antibiotics such as telithromycin, clarithromycin, erythromycin

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in people who take it. Do not drive a car, operate machinery, or do other dangerous activities until you know how KALYDECO affects you.
- Avoid flavor and fragrance oil grapefruit while you are taking KALYDECO.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **liver problems: Tell your doctor right away if you have any of the following symptoms while taking KALYDECO:** Your doctor will do blood tests to check your liver.
  - before you start KALYDECO
  - in the first 1 month after you start taking KALYDECO
  - every year while you are taking KALYDECO

  For people who have had high liver enzymes or liver disease, your doctor may want to check the liver more frequently.
  Call your doctor right away if you have any of the following symptoms:
  - pain or discomfort in the upper right abdomen (stomach area)
  - yellowing of your skin or the white of your eyes
  - loss of appetite
  - nausea or vomiting
  - pain, swelling, or tenderness
- **Serious allergic reactions** have happened in people who have taken KALYDECO. Call your healthcare provider or go to the emergency room right away if you have any of the following symptoms: Symptoms of an allergic reaction may include:
  - rash
  - tightness of the chest or breathing or difficulty breathing
  - swelling of the face
- **Abnormality of the eye (cataract).** Your doctor should have your eyes checked before and while taking KALYDECO. Your doctor should perform eye examinations every 12 months while taking KALYDECO.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection, including:
  - nasal congestion
  - sinus congestion
  - sinus pain
  - sinus infection
- stomach pain
- diarrhea
- dizziness
- rash

Tell your doctor if you have any side effects that bother you or that do not go away. Please ask your doctor or pharmacist for more side effects of KALYDECO. For more information, see the Patient Information.

Use of KALYDECO in children ages 6 years and older with CF who have a G551D mutation in the CFTR gene is based on results from 247 subjects who have been evaluated for up to 96 weeks in clinical studies.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the Important Safety Information, the Patient Information, and the Important Information for People with CF.

Please click here to view the full Prescribing Information, including the Patient Information.

People with CF pictured may or may not be KALYDECO patients.

KALYDECO® (ivacaftor) is a prescription medicine for people ages 6 years and older with CF who have at least one mutation in the CFTR gene that is responsive to KALYDECO. It is not known if KALYDECO is responsive to KALYDECO.

KALYDECO may not be right for you if you have an individual CF gene mutation.

KALYDECO is not for people with CF who are not taken under 6 months of age.

Please click here to view the full Prescribing Information, including the Patient Information.

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Age 12 years and older

Study 1

Study 1 was a 48-week study in which 185 patients **age 12 and older** with a G551D mutation received KALYDECO (150 mg tablets) or placebo with fat-containing food every 12 hours, along with their other cystic fibrosis (CF) treatments. Results from the primary analysis of the overall population (including 24 adult patients) took all their other CF treatments except inhaled hypertonic saline through the entire length of the study (48 weeks). The study evaluated lung function (FEV$_1$). Other results studied were CF respiratory symptoms, pulmonary exacerbations, sweat chloride, and growth. The study also evaluated the safety of KALYDECO.

Pulmonary exacerbations, sweat chloride, or how much a person can exercise before a forced breath in 1 second.

Information eligible to enroll and included in this study was:

G551D

Study results

Lung function (FEV$_1$)

Lung function increased

10.6 percentage points greater average improvement, compared to placebo through 24 weeks.

10.5 percentage points greater average improvement, compared to placebo through 48 weeks.

Lung function in the mean measured with an FEV$_1$ test, which measures how much air a person can exhale in a forced breath in 1 second.

Other study results

CF respiratory symptoms improved

8.6 points on average, compared to placebo, from the start of the study through Week 48.

Respiratory symptoms are measured by the CFQ-R Respiratory Domain score, which is a tool used to measure respiratory symptoms, including coughing, mucus, and trouble breathing.

Pulmonary exacerbations

Pulmonary exacerbations decreased

Nearly 7 out of 10 people who take KALYDECO did not have a pulmonary exacerbation, compared to around 4 out of 10 people who took placebo at Week 48.

Pulmonary exacerbations are a sudden worsening of certain symptoms requiring a change in the use of oral, IV or inhaled antibiotics.

Weight

Weight increased

About 2.7 kg (~6 lb) on average, compared to placebo at Week 48.

Sweat chloride

After taking KALYDECO:

Sweat chloride decreased on average by -48 mmol/L, compared to placebo through Week 48

Sweat chloride is a measure of the amount of salt in a person's sweat. **A decrease in sweat chloride levels does not mean there will be an improvement in lung function (FEV$_1$).**

Study 2

Study 2 was an 8-week study in which **patients age 6 and older** with 1 copy of the F508del mutation and a second mutation predicted to be responsive to KALYDECO took either KALYDECO (150 mg tablets) or placebo every 12 hours, along with their other CF treatments. The study evaluated lung function (FEV$_1$), CF respiratory symptoms and safety were studied.

In this study, 156 people took KALYDECO (150-mg tablets) and 161 people took placebo.

Mutations enrolled in this study were:

2789+5G>A, 3659delC, 3849+10kbC>T, 2143delT, 4015delA, 2184delA, 2183AA>G, 2307delA, 2347delG, R117C, R347H, R352Q, S945L, S977F.

Important considerations

- **Results varied by mutation.** Not all mutations showed the same level of benefit when taking KALYDECO.
- Some people experienced less improvement compared to the average for all the people in the study. Others experienced more improvement.
- This is not intended to represent the full study design or results.
- Talk to your healthcare provider for more information.

Study results

Lung function (FEV$_1$)

Lung function increased

In the overall population studied, lung function increased by 4.7 percentage points greater average improvement, compared to the average for all the people in the study. Others experienced more improvement.

This is not intended to represent the full study design or results.

Talk to your healthcare provider for more information.

Other study results

CF respiratory symptoms improved

CF respiratory symptoms improved

In the overall population studied, CF respiratory symptoms improved by 8.7 points on average, compared to placebo from the start of the study to the average of Week 4 and Week 8.

Results varied by mutation.

Lung function in the mean measured with an FEV$_1$ test, which measures how much air a person can exhale in a forced breath in 1 second.

Back to top ▲

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people ages 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to see if it may be a medicine for you.

KALYDECO is not for people who are not CF patients.

KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Keep a list of them to show to your doctor who prescribes medicines for you and to show to your doctor or pharmacist for a list of medicines that are safe to take.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIMAMYCIN® RIFATER®) or rifabutin (MYCOBUTIN®)
- voriconazole (VFEND®), posaconazole (Noxafil®), itraconazole (TEGRITOL®, CARBATROL®, EQUETROL®), fluconazole (DIFLUCAN®), or ketoconazole (NIZORAL®), ketoconazole (NYDRAZID®), or ketoconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

KALYDECO can cause dizziness in people who take it. If you experience dizziness, do not drive, operate machinery, or do something else dangerous.

- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver
- Call your doctor right away if you have any of the following symptoms of liver problems:
  - pain or discomfort in the upper right stomach (abdomen) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - unusual tiredness
- **Serious allergic reactions** have happened in people who are taking with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light headedness or dizziness

Abnormality of the eye lens (cataract), which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations if your child is at increased risk for development of cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold) including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not the possible side effects of KALYDECO. For more information, ask your healthcare pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 years has been in a pregnancy lasting (gestational age) less than 37 weeks has not been studied.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Safety & Side Effects

How the safety information was assessed in clinical studies

Serious and most common side effects

Additional safety considerations

The overall safety profile of KALYDECO is based on data from 3 placebo-controlled studies. The safety data from the 3 clinical studies were combined and reviewed together, or "pooled," to arrive at the profile for adults for KALYDECO.

Across these studies, a total of 353 people ages 6 years and older with the G551D mutation (Studies 1 and 2) or one copy of the F508del* mutation (Study 3) in their CFTR gene took KALYDECO or placebo every 12 hours with fat-containing food. 221 people received KALYDECO and 132 people received placebo.

*KALYDECO is not approved and is not effective in people with cystic fibrosis (CF) who have only the F508del mutation (F508del/F508del) in the CF gene.

In addition, safety was assessed in the following clinical studies:

- **Study 4:** Study of KALYDECO in 39 people with CF age 6 years and older with **G1244E, G1349D, G178R, G551S, G970R,** I507T, **S1251N, S1255P, S549N,** or S549R mutation. Participants in the study took KALYDECO (150-mg tablets) or placebo every 12 hours with fat-containing food. Each person had an F508del mutation on their second KALYDECO and an 8-week treatment period with placebo
- **KALYDECO is not indicated for people with CF who have the G970R mutation.**
- **Study 5:** A 24-week study in which 52 children with CF age 6 years and older with CF age 6 years and older with an **R117H** mutation. People in this study took KALYDECO (50-mg or 75-mg oral granules) every 12 hours with fat-containing food. No one in this study took placebo
- **Study 7:** An 8-week study in which KALYDECO was studied in 3 children with CF age 2 to less than 6 years with a **G551D** or **S549N** mutation. All children in this study took KALYDECO (50-mg or 75-mg oral granules) every 12 hours with fat-containing food. No one in this study took placebo
- **Study 8:** A 24-week study in which KALYDECO was studied in 34 children with CF age 2 to less than 6 years with a **R117H** mutation. All children in this study took KALYDECO oral granules every 12 hours with fat-containing food. No one in this study took placebo

The safety profile for Studies 4, 5, 6, 7, and 8 was similar to that observed in Studies 1 and 2.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used to treat the underlying cause of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to see if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney disease
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (ELANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, azithromycin (ZIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness

- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effects that bother you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **Full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Safety & Side Effects

How the safety of KALYDECO was assessed in clinical studies	Serious and most common side effects	Additional safety considerations

Remember, this website is for informational purposes only and is not intended to be a substitute for professional medical advice. You should talk to your healthcare provider about the clinical study results and the possible side effects of KALYDECO.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

High liver enzymes in the blood, which have happened in people receiving KALYDECO.

Your doctor will do blood tests to check your liver:

- before you start KALYDECO
- every 3 months during your first year of taking KALYDECO
- every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

Serious allergic reactions have happened to people who are treated with KALYDECO.

Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:

- rash or hives
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- light-headedness or dizziness

Abnormality of the eye lens (cataract), which has happened in some children and adolescents receiving KALYDECO.

Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

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What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (EES® Tablet)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
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- rash
- nausea
- dizziness

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Use of KALYDECO in children aged 1 month to less than 4 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Safety & Side Effects

How the safety of KALYDECO was assessed in clinical studies

Serious and most common side effects

Additional safety considerations

Before taking KALYDECO®

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

Antibiotics

rifampin
(RIFAMATE®, RIFATER®)

rifabutin
(MYCOBUTIN®)

Seizure medicines

phenobarbital

carbamazepine
(TEGRETOL®, CARBATROL®, EQUETRO®)

phenytoin
(DILANTIN®, PHENYTEK®)

Herbal supplement

St. John's wort

Antifungal medicines

ketoconazole

itraconazole
(SPORANOX®)

posaconazole
(NOXAFIL®)

voriconazole
(VFEND®)

fluconazole
(DIFLUCAN®)

Antibiotics

telithromycin

clarithromycin
(BIAXIN®)

erythromycin
(ERY-TAB®)

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

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KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- stomach (abdominal) pain
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting gestational age less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **Full Prescribing Information**, including **Patient Information**

People with CF pictured may or may not be taking KALYDECO.

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How to Take KAUCYRO®

Take KAUCYRO once 12 hours after your evening meal or bedtime snack.

- Taking KAUCYRO with food helps your body keep enough medicine in the body. Taking KAUCYRO without food may increase 12 hours to tell the same story about the medicine.
- Your healthcare provider may prescribe a different dose or frequency for KAUCYRO.

Always take KAUCYRO with the same schedule.

- Taking KAUCYRO at different times of the day or at different times before starting a meal may change how your body uses KAUCYRO.
- Do not take other medicines or supplements before starting, during, or after taking KAUCYRO. Tell your healthcare provider about all other medications, vitamins, herbal supplements and over-the-counter medicines, vitamins, and herbal supplements.

Watch a short video on how to take KAUCYRO:

Scan the KAUCYRO QR Code for Rx only

To learn how to take KAUCYRO and what to expect, scan the QR code or visit www.KAUCYRO.com.

Watch the **Important Safety Information** and **Risk Prevention Information** videos in **Patient Information**.

Scan the Rx only KAUCYRO QR Code

How KAUCYRO and generic are packaged?

KAUCYRO is supplied as oral tablets in a bottle of 30 tablets and in blisters for their 8 pack and

Short Grace and Same Year to take KAUCYRO and generic

Each box of KAUCYRO and generic contains 30 tablets. Each tablet is a 25 mg oral tablet.

Each box of generic contains 30 tablets. This is enough for a week based on the 12 hours to take KAUCYRO and generic as recommended by your healthcare provider. Your healthcare provider may prescribe a different dose or frequency for KAUCYRO. Use the appropriate dose based on your healthcare provider.

KAUCYRO and generic recommended doses

If your vital is:

3 months to less than 3 months old

Oral weight:

3 kg or more

2.75 to 3 kg

The recommended dose is:

Total daily dose: 12.5 mg

Total daily dose: 11.6 mg

If your vital is:

3 months to less than 6 months old

Oral weight:

5 kg or more

4.5 to 5 kg

The recommended dose is:

Total daily dose: 15 mg

Total daily dose: 13.8 mg

If your vital is:

6 months to less than 8 years old

Oral weight:

7 kg or more

6.5 to 7 kg

The recommended dose is:

Total daily dose: 17.5 mg

Total daily dose: 16.2 mg

If your vital is:

8 years old and older

Oral weight:

11 kg or more

10 to 11 kg

The recommended dose is:

Total daily dose: 20 mg

Total daily dose: 18.4 mg

If your vital is:

6 months to less than 8 years old

Oral weight:

7 kg or more

6.5 to 7 kg

The recommended dose is:

Total daily dose: 17.5 mg

Total daily dose: 16.2 mg

If your vital is:

8 years old and older

Oral weight:

11 kg or more

10 to 11 kg

The recommended dose is:

Total daily dose: 20 mg

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4.5 to 5 kg

The recommended dose is:

Total daily dose: 15 mg

Total daily dose: 13.8 mg

If your vital is:

6 years old and older

Oral weight:

7 kg or more

6.5 to 7 kg

The recommended dose is:

Total daily dose: 17.5 mg

**Total daily dose: 16.2

How to Take KALYDECO®

Take KALYDECO every 12 hours or as directed by your healthcare provider

- Taking KALYDECO every 12 hours helps keep enough medicine in the body
- Remember, taking KALYDECO every 12 hours is not the same as taking it twice a day
- Your healthcare provider may prescribe a different dose or frequency for KALYDECO

Always take KALYDECO with fat-containing food

- Fat-containing food helps the body absorb KALYDECO better

See examples of fat-containing foods

- Avoid foods and drinks that contain grapefruit, as these may affect the amount of KALYDECO in the body

Take KALYDECO, plus all your other cystic fibrosis (CF) therapies, exactly as your healthcare provider tells you to take them

- Be sure to talk to your healthcare provider before starting, changing, or stopping any CF therapies or other medications, including prescription and non-prescription medicines, vitamins, and herbal supplements

Before you start taking KALYDECO, **be sure KALYDECO is right for you.**

To learn how to take KALYDECO oral granules or tablets, from how they're supplied to step-by-step instructions, choose one below.

How to take KALYDECO oral granules	How to take KALYDECO tablets

KALYDECO is supplied as tablets (150 mg) for people 6 years and older.

- Each KALYDECO box contains 4 individual blister cards. Each blister card contains 14 pills—7 morning doses and 7 evening doses

Not actual size.

How often should you take KALYDECO tablets?

- Take KALYDECO every 12 hours with fat-containing food unless otherwise directed by your healthcare provider
- Your healthcare provider may recommend a different dose or frequency for KALYDECO. Take KALYDECO exactly as your doctor tells you to take it

What if you miss a dose of KALYDECO?

If you miss a dose of KALYDECO and it is **within 6 hours** of when you usually take it, take the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

If you miss a dose and it is **more than 6 hours** after the time you usually take it, **skip that dose** only and take the next dose with fat-containing food when you usually take it. Do **not** take 2 doses at the same time to make up for a missed dose.

FAQs
Read the answers to questions you may have about KALYDECO.

Patient Stories With KALYDECO
Read stories from the KALYDECO community.

What is KALYDECO® (ivacaftor)?

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- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of those medicines if you are unsure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifapentine (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRIO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
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What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
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The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

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Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **Full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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BEYOND ONE GENE

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kalydeco (ivacaftor) VERTEX

MENU

Fat-Containing Food Ideas

Looking for fat-containing food ideas?

Every dose of KALYDECO® must be taken with a meal or snack that contains fat to help your body absorb the medicine. You can get some delicious food ideas below. Remember to talk to your healthcare provider or dietitian before making any changes to your diet.

Easy ways to add fat to your foods
Drizzle extra-virgin olive oil
Mix in sliced almonds

Spread on butter
Mash in avocado

Morning meals	Evening meals
Oatmeal with whole milk, almonds, and fruit	Tater tot bake
Bagel with peanut butter	Pasta with meat sauce
Overnight oats with whole milk and blueberries	Macaroni and cheese
Whole-milk yogurt sweetened with sliced fresh fruit	Quesadilla with whole-milk cheese
Chocolate chip pancakes	Whole-milk cheese pizza

Quick snacks for when you're on the go
Chocolate pudding
Whole-milk mozzarella string cheese
Hard-boiled eggs
Multigrain toast with cream cheese and jelly
Strawberry whole-milk yogurt milkshake
Peanut butter with celery

When taking KALYDECO, avoid foods and drinks that contain grapefruit as these may affect the amount of KALYDECO in the body.

These lists are not intended to be complete. Not all foods may be appropriate for children. Talk to your loved one's healthcare provider if you have questions about age-appropriate fat-containing food options.

Visit fdc.nal.usda.gov for foods and their fat content.

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Call your doctor right away if you have any of the following symptoms of liver problems:

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The most common side effects of KALYDECO include:

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For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Resources

Stories · Videos · Downloadable Resources · FAQs

Age 6, CRPS

Michael and Kathleen's Journey
Watch Now

Every story is unique. KALYDECO brings them together.

"We were excited to get our son started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

1/6

Hear from the KALYDECO community

Cooper
Age 11, Months: 000000

Watch Cooper's story

Kai Kersten and Kathleen, siblings to Michael

For Kersten and Kathleen, siblings to Michael, CRPS

My son Kathleen is 7 years old. He loves soccer, baseball, fishing, and just being outside.

Read More

Michael
Age 6, Months: 000000

Watch Michael and Kathleen's Journey

Michael, Kathleen and Cooper, siblings to Kai, Pseudomonas Infection, CRPS

Michael and Kathleen are siblings. Kathleen is 9 years old and Michael is 6 years old. Kathleen and Michael are both diagnosed with Cystic Fibrosis and Pseudomonas Infection.

Read More

Carter
Age 3, Months: 000000

Watch Carter's story

Carter's mom, Amanda

Carter loves dinosaurs and is a very sweet and caring little boy with a lot of energy.

Read More

All content

Cooper
Age 11, Months: 000000

Watch Cooper's story

Cooper's mom, Amanda

Brady got an early start with KALYDECO

Cooper's mom, Amanda, shares how, since Brady, an KALYDECO, at age 2, KALYDECO has had the right decision for Cooper.

Watch

Carter
Age 3, Months: 000000

Watch Carter's story

Carter's mom, Amanda

Kaitlin finds strength in her support system

I have 2 boys, and I love spending time outdoors with my family. My son Carter is fishing, and he is huge part of my life.

Read More

Carter
Age 3, Months: 000000

Watch Carter's story

Carter's mom, Amanda

Vertex GPS™ Guidance & Patient Information for KALYDECO

Carter's mom shares how KALYDECO would be the best option for her, and we were ready to start treatment.

Read More

Cooper
Age 11, Months: 000000

Watch Cooper's story

Cooper's mom, Amanda

Amanda teaches Cooper the importance of taking his medicines

Cooper's mom, Amanda, shares that, she is very proud and excited for Cooper, and he has the chance grow and live his dreams.

Watch

Michael
Age 6, Months: 000000

Watch Michael's story

Michael's mom, Amanda

For Kersten and Kathleen, siblings to Michael, CRPS

My son Kathleen is 7 years old. He loves soccer, baseball, fishing, and just being outside.

Read More

Carter
Age 3, Months: 000000

Watch Carter's story

Carter's mom, Amanda

Brady is passionate about his mom and his family

Brady's mom shares how a passion of mine, was KALYDECO, and how, since Brady's on KALYDECO, he has a lot more energy.

Watch

Carter
Age 3, Months: 000000

Watch Carter's story

Carter's mom, Amanda

Carter's dream is to be a soldier

Carter's mom shares KALYDECO from my son's point of view, and how, since Carter started on KALYDECO, he has been

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Videos

Watch Video

Watch Video

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Resources

Stories · Videos · Downloadable Resources · FAQs

"We were grateful that we were able to get Emily on KALYDECO as soon as we heard it was approved."

—Brandy Lynette, Alissa and Don

Hear from the KALYDECO community

For Kelsey and Madison, whistling is a sweet sound.

Hy said Madison's 7-year-old. He loves sports, science, music, fishing, and just being outside.

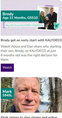
Read More

Carter stays diligent about taking his KALYDECO medicine.

Carter's Dad knows KALYDECO from his own. During one of his appointments, Carter asked his doctor if he could try KALYDECO.

Read More

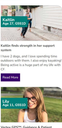
All content



Brody got an early start with KALYDECO.

Kylie's mom and dad, Jessica and Brian, know, firsthand, how quick, on KALYDECO, at just 6 months old, Brody was the right decision for Kylie.

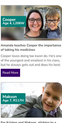
Watch



Kylie's Mom, Jessica, is very strong and caring.

Kylie's Dad, Brian, is a hard-working, family-oriented man.

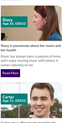
Read More



Kaitlin finds strength in her support system.

Chase 2 drops, and Chase spending time with family and friends, Kaitlin's Dad, Brian, is having a lot of fun playing with her.

Read More



Amelia teaches Connor the importance of taking his medicine.

Connor's Dad, Jeremy, knows that his son are unique and wonderful in his own way. Connor's Mom, Jessica, gets out and does his best.

Read More

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Hy said Madison's 7-year-old. He loves sports, science, music, fishing, and just being outside.

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Videos

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How to Take KALYDECO? Oral Granules

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Learn about KALYDECO

Are there any possible side effects of KALYDECO?

This brochure provides information on KALYDECO (ivacaftor), a medicine for people 2 children ages 2 and up who have at least one mutation in the CFTR gene that is not F508del or G551D.

View

Discover Resources en Español

Learn how to take KALYDECO

A Guide to KALYDECO (Tablets)

This brochure provides information on KALYDECO (ivacaftor), a medicine for people 6 years and up who have a G551D mutation.

View

FAQs

Tablets and granules · Tablets only · Granules only

What is KALYDECO?

Does KALYDECO treat cystic fibrosis (CF)?

Who is KALYDECO for?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing foods?

Are there any possible side effects of KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked while taking KALYDECO?

**How

Resources

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Caregiver brings them together.

Age 13, KAUVEDO

Photo courtesy of Carter's family

Every story is unique. KAUVEDO brings them together.

We're grateful for KAUVEDO

—Lily's mom, Carissa

3 / 5

Hear from the KAUVEDO community

Carter
Age 13, Months: 0/0/0

Watch Carter's story with KAUVEDO

Hear Kristen and Shalom, relishing in life with KAUVEDO

My son Hakeem is 7 years old. He loves swimming, kayak, fishing, and jet boring.

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Kristen
Age 3, Months: 0/0/0

Kristen feels stronger in her support system

I have 2 dogs, and I love spending time with them and my family. I love to go to the beach. Fishing and kayaking is a huge part of my life with my family.

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Carter
Age 13, Months: 0/0/0

Carter stays diligent about taking his KAUVEDO

I think I heard about KAUVEDO from my mom. During one of my appointments she asked my doctor if I knew the KAUVEDO medicine.

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Carter
Age 13, Months: 0/0/0

Brady got an early start with KAUVEDO

Carter loves his family, his friends, and his dogs. Jesse, an KAUVEDO, at grand rounds, Carter and his family discussed the

Watch

Kristen
Age 3, Months: 0/0/0

Kristen feels stronger in her support system

I have 2 dogs, and I love spending time with them and my family. I love to go to the beach. Fishing and kayaking is a huge part of my life with

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Carter
Age 13, Months: 0/0/0

Carter stays diligent about taking his KAUVEDO

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Carter
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Hakeem
Age 7, Months: 0/0/0

Hear Kristen and Shalom, relishing in life with KAUVEDO

My son Hakeem is 7 years old. He loves swimming, kayak, fishing, and jet boring.

Read More

Carter
Age 13, Months: 0/0/0

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I think I heard about KAUVEDO from my mom. During one of my appointments she asked my doctor if I knew the KAUVEDO

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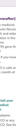

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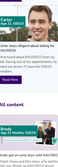
Apr 21, 2022

Every story is unique. KALYDECO brings them together.

"It's so exciting and rewarding to be able to help spread awareness about CF."

Hear from the KALYDECO community


Watch
Apr 21 Months, 00:00
Kalyn
Kalyn's Journey
Watch
Kai Erickson and Kalyn, attending to a cookie.
My son Kalyn is 7 years old. He loves science, baking, fishing, and just being outside.
Read More
Carter Lindsay
Carter's Journey
Watch
Apr 21 Months, 00:00
Carter
Carter's Journey
Watch
Apr 21 Months, 00:00
Kaitlin
Kaitlin's Journey
Watch
Apr 21 Months, 00:00
Carmen
Carmen's Journey
Watch
Apr 21 Months, 00:00
Kaylee
Kaylee

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Hear from the KALYDECO community
Every story is unique. KALYDECO brings them together.
"I enjoy being outdoors and being active."
Watch
Watch
Watch

Resources

Age: 2, 2020

"Every story is unique. KALYDECO brings them together."

Every story is unique. KALYDECO brings them together.

"We were excited to get Cooper started and believed it would benefit him in the long run."
– Cooper's mom, Amanda

5:24

Watch on YouTube

Watch Jackson's story

Watch Cooper's story

Watch Amanda's story

Watch Carter's story

Watch Kaitlin's story

Watch Kevin's story

Watch Jessica's story

Watch Jessica

Patient Stories

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Kate, 4 years
Kavdeco user

"Kayan and all Kavdeco staff are so helpful and kind."

Every story is unique. KAVDECO brings them together.

"We were excited to get Kavdeco, it was recommended to us and benefit him to the long run. ..."
— Cooper's mum, Amanda.

Kate, 4 years
Kavdeco user

Hear from the KAVDECO community

Kate, 4 years
Mum, 43, DISCO, Scotland

Story is passionate about her music and her family

Kate's passion for music has been her greatest ally in her fight against eosinophilic esophagitis. Her mum shares how she was able to return to the o music teacher since it was 3 years ago.

Before kavdeco, Kate's mum shares how she was 6 years old, a genetic test discovered the presence of the EoE gene. Kate's mum shares how Kate's condition affected her life, her activities, had to stop her sweet 16 7 food allergies.

Kate's mum shares how she was so desperate and important to have a voice relationship with Kavdeco. Kate's mum shares how Kavdeco helped her family and how Kate's life has improved since she heard about KAVDECO. Kate's mum shares how Kate's life has improved since she heard about KAVDECO.

My family felt it would be a great choice to support Kavdeco because of the amazing work Kavdeco does for the community. Kate's mum discussed the possible side effects of Kavdeco and how Kate's life has improved since she heard about KAVDECO.

It's always important to be in the loop with what's going on in the world of EoE and Kate's mum shares how Kate's life has improved since she heard about KAVDECO. Kate's mum shares how Kate's life has improved since she heard about KAVDECO. Kate's mum shares how Kate's life has improved since she heard about KAVDECO.

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Kayan, 4 years
Mum, 43, DISCO, Scotland

Kayan's Journey: Resilience, Hope, and Support

For Kayan and Kayan's family, living with eosinophilic esophagitis (EoE) has been a journey marked by challenges, resilience, and the search for effective support. Diagnosed at 4 years old, Kayan's condition has profoundly impacted her daily life, affecting her ability to enjoy meals and participate in social activities. The family's journey has been filled with frustration, but also with hope and gratitude for the support they have received from Kavdeco.

Before Kavdeco, Kayan's family faced significant challenges in managing her EoE. The lack of awareness and understanding of the condition made it difficult to find the right support and treatment. The family felt isolated and overwhelmed by the complexity of the disease and the lack of resources available to them.

Read More

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Mum, 43, DISCO, Scotland

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Kate, 4 years
Mum, 43, DISCO, Scotland, Kavdeco user

Story: Kate's Journey with Eosinophilic Esophagitis and Support from Kavdeco

Kate's journey with eosinophilic esophagitis (EoE) has been a challenging one, marked by frustration, but also by hope and gratitude for the support she has received from Kavdeco. Diagnosed at 6 years old, Kate's condition has profoundly impacted her daily life, affecting her ability to enjoy meals and participate in social activities. The family's journey has been filled with frustration, but also with hope and gratitude for the support they have received from Kavdeco.

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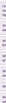
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Cooper, 4 years
Mum, 43, DISCO, Scotland

Cooper's Journey: Resilience, Hope, and Support from Kavdeco

Cooper's journey with eosinophilic esophagitis (EoE) has been a challenging one, marked by frustration, but also by hope and gratitude for the support he has received from Kavdeco. Diagnosed at 4 years old, Cooper's condition has profoundly impacted his daily life, affecting his ability to enjoy meals and participate in social activities. The family's journey has been filled with frustration, but also with hope and gratitude for the support they have received from Kavdeco.

Before Kavdeco, Cooper's family faced significant challenges in managing his EoE. The lack of awareness and understanding of the condition made it difficult to find the right support and treatment. The family felt isolated and overwhelmed by the complexity of the disease and the lack of resources available to them.

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Videos

Kate, 4 years
Mum, 43, DISCO, Scotland

Kate **Intermittent Safety Information** and **Patient Information** for KAVDECO

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How to Take KAVDECO? Oral Exercise

Downloadable Resources

Learn about KAVDECO

A Guide to KAVDECO Chelsea

This brochure provides information on KAVDECO for children aged 4 years and 5 years and 6 years old.

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FAQs

Ask a question | Search for answers

A Guide to KAVDECO Chelsea

This brochure provides information on KAVDECO for children aged 4 years and 5 years and 6 years old.

Learn more about KAVDECO

Stories Videos Downloadable Resources FAQs

- What is KAVDECO?
- Does KAVDECO cure eosinophilic esophagitis?
- How does KAVDECO work?
- I have 2 copies of the FOXP3 gene, am I eligible for KAVDECO?
- What should I tell my doctor before taking KAVDECO?
- What should I avoid while taking KAVDECO?
- What are the possible side effects of KAVDECO?
- Why do I need my liver enzymes checked every 3 months?
- Is KAVDECO safe to take long-term?
- What should I take KAVDECO?
- Can I take a break from KAVDECO with the containing food?
- Intermittent safety information about KAVDECO. Where should I talk to?
- Where can I find KAVDECO prescription fillers?

What is KAVDECO? (mouthfilm)

KAVDECO (budesonide oral suspension) is used for the treatment of Lymphocytic Esophagitis (LE) in adults. LE is a type of eosinophilic esophagitis (EoE) and is a chronic condition. Mouthfilm is a medicine that contains budesonide and is a corticosteroid. It is a medicine that reduces inflammation in the body.

Talk to your doctor to learn if you have an allergic reaction to budesonide or any other ingredients in KAVDECO.

IMPORTANT SAFETY INFORMATION

Before taking KAVDECO, tell your doctor about your medical conditions, including if you:

- have liver or kidney problems
- have a history of bone fracture, osteoporosis, or bone density loss. Patient information for a list of medicines
- are pregnant or plan to become pregnant. It is not known if KAVDECO will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if KAVDECO passes into your breast milk. You and your doctor should decide if you will take KAVDECO or not while you are breastfeeding.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with KAVDECO. Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine.

Do not take KAVDECO with any of the following:

- ketoconazole (NIZORAL®)
- itraconazole (SPORANOX®)
- ritonavir (NORVIR®)
- cobicistat (TYBOST®)
- cobicistat-containing products, e.g. STRIBILD®, GENVOYA®, PREZCOBIX®, PREZISTA®
- cobicistat-containing products, e.g. COBIFOR®, COBIFOR®, COBIFOR®, COBIFOR®

Tell your doctor if you have any of the following:

- Fungal infection in your mouth (oral thrush) and throat (esophageal thrush)
- Tuberculosis (TB)
- Herpes simplex virus (HSV) infection of the eyes
- Cataracts
- Glaucoma
- Adrenal gland problems
- Stress situations (such as injury, hospitalization, surgery, or severe illness)

Your doctor will prescribe KAVDECO only if the benefits outweigh the risks.

Do not stop taking KAVDECO without your doctor's approval.

Do not share your KAVDECO with other people.

What are the possible side effects of KAVDECO?

Some common side effects include:

- **Fungal infection in the mouth** (oral thrush) and throat (esophageal thrush). Your doctor may prescribe an antifungal medicine to treat oral thrush. Rinsing your mouth with water after taking your KAVDECO may help reduce oral thrush.
- **Bone density loss.** Your doctor may prescribe medicines to prevent bone density loss.
- **Cataracts.** Your doctor may prescribe medicines to treat cataracts.
- **Glaucoma.** Your doctor may prescribe medicines to treat glaucoma.
- **Adrenal gland problems.** Your doctor may prescribe medicines to treat adrenal gland problems.
- **Stress situations** (such as injury, hospitalization, surgery, or severe illness).

The most common side effects of KAVDECO are:

- nasal congestion
- sinus infection
- cough
- nausea
- vomiting
- diarrhea
- abdominal pain
- gas
- bloating
- stomach discomfort
- upset stomach
- indigestion
- nasal or sinus congestion

Talk your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KAVDECO.

Tell your doctor if you have any side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the KAVDECO Patient Information, including "Important Safety Information" and "Patient Information".

Prescribe KAVDECO

Find a KAVDECO provider

Find out whether your insurance will cover KAVDECO

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Stories · Videos · Downloadable Resources · FAQs

Age 6, LDSP

Discussed with his doctor

Treated with KALYDECO

Every story is unique. KALYDECO brings them together.

"We were excited to get our daughter started and believed it would benefit him in the long run."

— Cooper's mom, Amanda

Hear from the KALYDECO community

Age 6, LDSP

Discussed with his doctor

Treated with KALYDECO

Cooper says diagnosis saved baking life

KALYDECO helped a boy with CF feel his best. During one of his appointments, he asked his doctor if he could start baking with his grandmother, and she said yes. Now, he's a passionate gluten-free baker and enjoys making his family's favorite treats. Learn how KALYDECO, the doctor-first and only-second CFTR modulator, helped Cooper and his grandmother bring homemade treats back into their lives.

When Cooper's parents first brought his CF diagnosis to his doctor's attention, they were concerned about his growth and his lung function. Cooper's doctor noticed that he was more suited to have a lung transplant than a lung function test.

Cooper's family was excited to get his treatment with KALYDECO underway. Since starting treatment, Cooper's lung function has improved, and he's gained weight. Cooper's mom, Amanda, made sure Cooper's care team knew that she was ready to start a new chapter in her family's life.

Tap **Important Safety Information** and **Full Prescribing Information** for **Patient Information**.

Read More

Age 12, LDSP

Discussed with his doctor

Treated with KALYDECO

Blaze's accomplishments ahead! Hear Amber and her family's story

Amber's life changed when Blaze's son was born. Her son's CF diagnosis, coupled with a difficult C-section, left Amber's family in ruins.

Read More

Age 6, LDSP

Discussed with her doctor

Treated with KALYDECO

Hope achieves its strong strength and wellness

Hope's dreams and hopes were passed on to her mother, Amber, who was diagnosed with CF at age 12. Hope's dreams and hopes were passed on to her mother, Amber, who was diagnosed with CF at age 12.

Read More

Age 12, LDSP

Discussed with his doctor

Treated with KALYDECO

Kyldillon finds strength in her support network

Chase's dogs, and how spending time with them helps him feel his best. Chase's family gathering is a huge part of his life. Learn how KALYDECO helps Chase's family.

Read More

Age 6, LDSP

Discussed with her doctor

Treated with KALYDECO

Cooper's Mom, Amanda, Shares Her Journey

Amanda teaches Cooper the importance of being a good friend and family.

Cooper loves doing his friends' do. He's also an artist, a singer and a musician. He's a big sister to his sister Ella and loves to dance.

Read More

Age 6, LDSP

Discussed with her doctor

Treated with KALYDECO

Cooper says diagnosis saved baking life

KALYDECO helped a boy with CF feel his best. During one of his appointments, he asked his doctor if he could start baking with his grandmother, and she said yes.

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AE content

Age 12, LDSP

Discussed with his doctor

Treated with KALYDECO

Brody get an early start with KALYDECO

Brody's dreams and hopes are for a bright future. Brody's dreams and hopes are for a bright future. Brody's mom and dad say their decision to start treatment with KALYDECO was the right decision.

Read More

Age 12, LDSP

Discussed with his doctor

Treated with KALYDECO

Kyldillon finds strength in her support network

Chase's dogs, and how spending time with them helps him feel his best. Chase's family gathering is a huge part of his life. Learn how KALYDECO helps Chase's family.

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Age 6, LDSP

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Videos

Tap **Important Safety Information** and **Full Prescribing Information** for **Patient Information**.

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How to Take KALYDECO® Oral Granules

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FAQs

Tablets and granules

Additional resources and support

Does KALYDECO® help with CF?

KALYDECO is a prescription medicine for people with CF ages 2 and older who have at least one mutation in the gene that makes the CFTR protein, including the following mutations: F508del, G551D, R117H, G1244E, G1349D, G970R, I148T, R352Q, S945L, S549N, S549R, G551S, G1244V, G1349V, G178R, S1251N, S1255P, D579G, R347H, R117C, L206W, R1070W, F1074L, D1152H, S1251N, S1255P, D579G, R347H, R117C, L206W, R1070W, F1074L, D1152H, and 2789+5G>A in at least one allele, based on results in clinical studies. It is not known if KALYDECO is effective in people who have other mutations in the gene that makes the CFTR protein.

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine for people ages 2 and older with CF who have at least one mutation in the gene that makes the CFTR protein, including the following mutations: F508del, G551D, R117H, G1244E, G1349D, G970R, I148T, R352Q, S945L, S549N, S549R, G551S, G1244V, G1349V, G178R, S1251N, S1255P, D579G, R347H, R117C, L206W, R1070W, F1074L, D1152H, S1251N, S1255P, D579G, R347H, R117C, L206W, R1070W, F1074L, D1152H, and 2789+5G>A in at least one allele, based on results in clinical studies. It is not known if KALYDECO is effective in people who have other mutations in the gene that makes the CFTR protein.

IMPORTANT SAFETY INFORMATION

What is KALYDECO®, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- have cataracts or have been told by ophthalmologists (a doctor who specializes in treating eye diseases) or optometrists (a doctor who specializes in vision care) that you may develop cataracts
- are pregnant or plan to become pregnant. It is not known if KALYDECO is harmful to an unborn baby.
- are pregnant and are taking KALYDECO. Pregnancy exposure registries for KALYDECO and other medicines that treat CF are available. There are ways to find out how KALYDECO affects you and your unborn baby while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO or breastfeed. Do not do both at the same time.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while taking KALYDECO?

Do not take KALYDECO with grapefruit or grapefruit juice, or Seville orange or Seville orange juice because these products can increase the amount of ivacaftor in your blood.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- high liver enzyme levels in blood tests, which may lead to liver problems. Your doctor should do blood tests before you start KALYDECO and after you start KALYDECO.
- cataracts. Children who have taken ivacaftor for more than 3 months have developed cataracts. Your doctor should do eye tests before you start KALYDECO and while you are treated with KALYDECO.

Your doctor should tell you if you are at increased risk for these side effects or any other side effects of KALYDECO. For more information, see the Full Prescribing Information.

Use of KALYDECO in children aged 2 years and older with CF who have at least one mutation in the gene that makes the CFTR protein that is not listed above has not been studied.

The most common side effects in people with CF are stomach and intestinal (gut) pain, diarrhea, rash, headache, and nasal stuffiness.

Tap Important Safety Information and Full Prescribing Information for Patient Information

Do not stop or change your medicine without talking to your doctor.

Call your doctor right away if you have any of these symptoms:

- allergic reactions (anaphylaxis, hives, rash, or itching)
- seizure
- severe muscle pain or weakness
- vision changes (cataracts, blurred vision, or decreased vision)
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any of these symptoms:

- headache
- nasal stuffiness
- upper respiratory tract infection (URI)
- sinusitis
- sore throat
- runny nose
- nasal or sinus congestion
- muscle pain

Your doctor also wants you to know that KALYDECO may cause other side effects. Talk to your doctor if you have any side effects that bother you or that do not go away. These are not all the possible side effects of KALYDECO. For more information, see the Full Prescribing Information.

Tap Prescribing Information or Full Patient Information

Do not stop taking KALYDECO without stop or change your medicine without talking to your doctor.

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Every story is unique. KAUTOECO helps them together.

"We were excited to get KAUTOECO because it would benefit him in the long run. ..."

— Cooper's mom, Amanda

Cooper & LEAH

Watch all 5 episodes of "Cooper's Story" and "Leah's Story"

Hear from the KAUTOECO community

Well Wishes and Walkers, sending hugs to Kaitlin!

My son Kaitlyn is 7 years old. He loves swimming, fishing, and just being outdoors.

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Carter's Mom, Amanda, Sending Hugs!

My son Kaitlyn is 7 years old. He loves swimming, fishing, and just being outdoors.

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Carter says diligent about taking his medication

I think about KAUTOECO from my son Kaitlyn's point of view. He is very diligent about taking his medication.

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Stress is passionate about her mom and her family

Stress has been a passion of mine, since my mom and her family started KAUTOECO.

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Carter says diligent about taking his KAUTOECO

I think about KAUTOECO from my son. Carter is very diligent about taking his medication.

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All content

Brody got an early start with KAUTOECO

Brody's mom, Michelle, shares how her son, Brody, on KAUTOECO at 2 months and now the right dosage.

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Mark strives to stay strong and active

Mark's mom shares how he has been active with. Chloe on adventures. I enjoy being outdoors, playing with my dog, and I love to ride my bike. Mark's mom shares how he has been active with. Chloe on adventures. I enjoy being outdoors, playing with my dog, and I love to ride my bike.

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Kaitlin finds strength in her support system

Kaitlin's dogs, and I love spending time with family and friends. Kaitlin finds strength in her support system. Kaitlin's dogs, and I love spending time with family and friends.

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Victoria GRIFFIN Outdoors & Patient Support Coordinator

Lily's doctors decided KAUTOECO would be the best option for her. Lily's doctors decided KAUTOECO would be the best option for her.

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Amanda Hutchins Cooper's Experiences of taking his medicines

Amanda Hutchins Cooper's son Cooper. Amanda Hutchins Cooper's son Cooper. Amanda Hutchins Cooper's son Cooper.

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For Kirsten and Hakeem, sticking to KAUTOECO

Kirsten and Hakeem, sticking to KAUTOECO. Kirsten, Hakeem, and just being outdoors.

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Videos

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Downloadable Resources

Learn about KAUTOECO

Learn how to take KAUTOECO

A Guide to KAUTOECO Tablets

Instructions for tablets and if and and when to take KAUTOECO and when to take KAUTOECO

View

FAQs

Treatment Options

Medical Conditions

Medical Appointments

What is KAUTOECO?

KAUTOECO is a prescription medicine. It is a medicine that is taken by mouth. It is used to treat people aged 2 years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, based on medical evidence that is expected to show a benefit in patients who have an mutation in the CFTR gene.

It is not known if KAUTOECO is safe and effective in children under 2 months of age.

IMPORTANT SAFETY INFORMATION

Before taking KAUTOECO, tell your doctor about all your medical conditions, including if you:

- have had an organ transplant other than a liver or hematopoietic stem cell transplant (e.g. a kidney transplant or a heart transplant). See the "Medicines you should not take" section below.
- are pregnant or plan to become pregnant. It is not known if KAUTOECO will harm your unborn baby. You and your doctor should discuss the potential benefit of KAUTOECO while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if KAUTOECO passes into breast milk. You and your doctor should decide if you will take KAUTOECO while breastfeeding.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

KAUTOECO may affect the way other medicines work, and other medicines may affect how KAUTOECO works. Ask your doctor or pharmacist for a list of medicines that interact with KAUTOECO.

Medicines that can affect KAUTOECO are:

- the antibiotics rifampin (RIFAMPIN®), rifabutin, rifapentine
- certain medicines such as ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, erythromycin, clarithromycin
- St Johns's wort
- antifungal medicines such as ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, erythromycin, clarithromycin
- antibiotics such as ciprofloxacin, azithromycin, and clarithromycin

Medicines you should not take while taking KAUTOECO:

- medicines that are sensitive to some people who take it. If you are taking medicines that are sensitive to KAUTOECO, KAUTOECO may increase the amount of these medicines in your blood.
- medicines or drink containing grapefruit juice or Seville orange juice

What are the possible side effects of KAUTOECO?

KAUTOECO can cause serious side effects, including:

- liver injury. Your doctor may check blood tests which have happened in people receiving KAUTOECO. Your doctor may do blood tests:
  - before you start KAUTOECO
  - during the first 3 months of your treatment with KAUTOECO
  - every year while you are taking KAUTOECO
- Allergic reactions. Allergic reactions happen in people who have cystic fibrosis and are treated with KAUTOECO. Call your doctor right away if you develop any of the following signs and symptoms:
  - rash
  - difficulty breathing
  - swelling of the face or throat
  - hives
  - fever
  - wheezing
  - cough
  - stomach pain
  - diarrhea
  - nausea
  - vomiting
  - dizziness
  - sore throat
  - pain in your joints
  - pain in your muscles
- Cataracts (clouding of the lens of the eyes). Your doctor should perform eye examinations before you start taking KAUTOECO. Your doctor should perform eye examinations while you are taking KAUTOECO. Tell your doctor if you have any changes in your vision.

The most common side effects of KAUTOECO include:

- headache
- nasal congestion
- infection
- rash
- nausea
- sore throat
- stomach pain
- diarrhea
- dizziness
- fever
- cough
- shortness of breath
- wheezing
- vomiting
- muscle pain
- joint pain

Call your doctor right away if you have any side effects.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KAUTOECO.

Call your doctor for medical advice about side effects.

KAUTOECO is children aged 6 years and older is found to be associated with a pregnancy lasting (gestational age) less than 37 weeks in clinical trials. Talk to your doctor if you are pregnant or plan to become pregnant.

KAUTOECO is children aged 6 years and older is found to be associated with a pregnancy lasting (gestational age) less than 37 weeks in clinical trials.

Call your doctor for medical advice about side effects.

See "Important Safety Information" and full Prescribing Information, including Patient Information.

Do not take KAUTOECO if you are allergic to any of its ingredients.

Jane
Age 6 | Colorado

"Brayan said GO around them so I could GO around them."

Every story is unique. Find the one that inspires you.
Watch more stories of people living with cystic fibrosis.

"We were excited to get Cooper started and believed Kalydeco would be a long-term

— Cooper's mom, Amanda

Cooper
Age 2 | Ohio

1 / 5

Hear from the KALYDECO community

Kaylee
Age 21 | Ohio

Kaylee finds strength in her support system

Kaylee's mom and her boyfriend have been a support system since she was diagnosed at age 3 with cystic fibrosis (CF). Kaylee's mom helped her through her treatments and her boyfriend helped her through her CF journey and he was there for her when she was in the hospital.

When I started taking KALYDECO, I noticed my lungs were clearer and I could breathe better. Since I started taking KALYDECO I've inspected my lungs and I can't even hear anything. I can't even hear anything in my lungs. I can breathe easily and comfortably. It's so exciting and relaxing to be able to breathe and not have to cough anymore.

I have a pretty amazing support system. My mom and my boyfriend are very caring and encouraging. I have boyfriend for almost 3 years, we've been together for almost 3 years. I'm very happy with him. He's very caring and he's very supportive.

KALYDECO has my lungs clearer. I have been able to breathe better. I can't even hear anything in my lungs. I can breathe easily and comfortably. I'm able to do more things and I'm able to go out and about and have more energy. I can do more things with my family and my friends. I can go to the beach, I can go to the pool, I can go to the lake, I can go to the park, I can go to the zoo, I can go to the aquarium.

See **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.

Carrie
Age 21 | Ohio

Carrie's dream of being a mom is now a reality

As Kristen and Matthew's sibling to a 2-year-old, Carrie's dreams of being a mom, being a teacher, and being a friend are now a reality.

Read More

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All content

Cindy
Cystic fibrosis mom

Cindy gets an early start with KALYDECO

Cindy's son Jonathan was diagnosed with cystic fibrosis (CF) at 3 months old. Cindy and her family are focused on Jonathan and their high-spirited daughter Ashley.

Watch

Kaylee
Age 21 | Ohio

Kaylee finds strength in her support system

Kaylee's mom and her boyfriend have been a support system since she was diagnosed at age 3 with cystic fibrosis (CF). Kaylee's mom helped her through her treatments and her boyfriend helped her through her CF journey and he was there for her when she was in the hospital.

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Kristen
Age 18 | Ohio

Kristen's dream of being a teacher is now a reality

Kristen SOPHY, Sophomore, & Patient Advocate, Ohio University

Cody's elections deadline KALYDECO provided Kristen with a sense of urgency to run for office.

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Watch Now

How to Take KALYDECO?
Oral Granules

Downloadable Resources

Learn about KALYDECO

A Guide to KALYDECO for Caregivers of Infants

This brochure provides information on KALYDECO for infants ages 4 months to 23 months who have cystic fibrosis (CF) and a gating mutation.

Download

A Guide to KALYDECO Tablets

Instructions for parents ages 6 years and older who have cystic fibrosis (CF) and a gating mutation.

View

FAQs

Frequently Asked Questions

Download as PDF

- What is KALYDECO?
- Was KALYDECO in cystic fibrosis (CF)?
- How does KALYDECO work?
- Is there a cure for cystic fibrosis (CF)?
- What should I ask my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?
- What are the possible side effects of KALYDECO?
- Why do I need my liver enzymes checked while taking KALYDECO?
- I have additional questions about KALYDECO. Who can I talk to?
- Where can I get KALYDECO?
- How is KALYDECO taken?

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used to treat people with cystic fibrosis (CF) ages 4 months and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is on the list of approved mutations.

Talk to your doctor to see if you have an approved CF gene mutation.

It is not known if KALYDECO is safe and effective in children with CF under 4 months of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any of its ingredients. See the end of Patient Information for a list of ingredients.
- are taking medicines for your heart, lungs, or blood pressure
- are taking medicines for your liver. You and your doctor should discuss if you will take KALYDECO and how your liver will be monitored.
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should discuss if you will take KALYDECO while you are breastfeeding.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may affect how KALYDECO works. Other medicines may be affected by KALYDECO. Your doctor will tell you if you can take medicines together.

Can you take KALYDECO if you have other medical conditions?

- pancreatic insufficiency
- cystic fibrosis-related diabetes
- osteopenia
- liver disease
- kidney disease

Tell your doctor if you have any other medical conditions.

Your doctor will decide if KALYDECO is right for you.

What should I avoid while taking KALYDECO?

- **High Grapefruit Products:** Do not eat grapefruit or drink grapefruit juice while taking KALYDECO. It may increase the amount of KALYDECO in your blood.
- **Hormonal Birth Control:** KALYDECO may reduce the effectiveness of hormonal birth control (such as birth control pills, patches, or vaginal rings). Your doctor may recommend a different form of birth control while you are taking KALYDECO.
- **Hormonal Birth Control Containing Oral Contraceptives:** Women who take hormonal birth control containing oral contraceptives should use a barrier form of birth control (such as condoms or diaphragms) while taking KALYDECO and for 5 days after stopping KALYDECO.

What are possible side effects of KALYDECO?

- headache
- diarrhea
- upper respiratory infection (stuffy nose, sinus pain, cold symptoms)
- nasal congestion
- rash
- nausea
- abdominal pain
- dizziness
- muscle pain
- vomiting
- rhinitis
- fever
- sinusitis
- throat irritation
- rhinorrhea
- pharyngitis
- dyspepsia
- rhinitis
- flatulence

See **Important Safety Information** and **full Prescribing Information**, including **Patient Information**, for KALYDECO.

Can you take KALYDECO if you have liver or kidney problems?

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Vertex Medical Information 1-877-404-8374 (1-877-404-VERTEX)
Vertex Medical Information Request
Vertex Pharmacovigilance
PP-KALYDECO-US-0000

Resources

> Every story is unique. KAVDECO helps them together.
>
> We were excited to get Kavdeco approved because it would benefit him in the long run. ...
>
> — Cooper's mom, Amarillo, Texas
>
> Cooper's CARE Journey

Physical and Occupational Therapy Services Covered

Every story is unique. KAVDECO helps them together.

> We were excited to get Kavdeco approved because it would benefit him in the long run. ...
>
> — Cooper's mom, Amarillo, Texas

Cooper's CARE Journey

Hear from the KAVDECO community

Vertex GPS™: Guidance & Patient Support Program

Lily's doctors decided KAVDECO would be the best option for her. Her mom and dad were in a little bit of a rush to get her on a new medicine to reduce changes in Lily. She is allergic to many medicines and has a very sensitive nature, so they needed to be sure it would work for her.

Vertex GPS™: Guidance & Patient Support Program has been beyond helpful during our journey. Lily's mom and dad have been very pleased with the support they have received from the Vertex GPS™ team.

Lily's mom, Carrie:

"**Important Safety Information** and **full Prescribing Information**, including **Patient Information**, is available."

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Our Kindness and Patience, Attending to a Genetic condition

My son Matteo is 7 years old. He loves Lego, Dinosaurs, Fishing, and just having fun.

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Stacy is passionate about her music and her family

Stacy is a mom of twins, and she loves passion in both of her children. Her son Ethan is a gamer, and his sister Lauren is a dancer.

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Cartier stays diligent about taking his KAVDECO

Cartier's mom, Jessica, shared that her son is a dad. During one of my appointments, he visited my office with his 2 kids.

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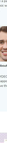

Brody got up early start with KAVDECO

Watch Alison and Dan share why starting their son Brody on KAVDECO was a no-brainer for them and why the right decision for

Watch

Mark strives to stay active and active

Mark's mom, Jessica, shared that his dad, Jeff, is a very active person who enjoys outdoor activities and hiking. Life with KAVDECO has been very

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Kylie finds strength in her support

Chase 2 days, and I love spending time with my family and friends. Life with KAVDECO has been a huge part of my life since I started

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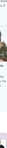

Amadeo teaches Cooper the importance of being a good friend

Cooper loves doing two theme do. He's one of the kindest people and cares about his friends.

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Jayne
Lower Back Pain

"Years and 10 surgeries later I finally found relief."

Every story is unique. KAUTDECO brings them together.

"My aura excited to get up and go. I felt like I could do it would benefit him in the long run."
— Cooper's mom, Amanda

"I felt like I could do it would benefit him in the long run."

Cooper
Amanda's Son

1 / 5

Hear from the KAUTDECO community

KAUTDECO
Carter
Age 10, DMD

Amanda teaches Cooper the importance of taking his medicine.

Cooper is a 10-year-old with Duchenne MD. He is the youngest and smallest in his class. Cooper's mom, Amanda, knows that he wants to be like his friends and that he can be active but frequent trips into hospitals are hard on his family.

Cooper's mom, Amanda, is proud of Cooper's gene mutation, we believe to be the cause of his DMD, because it has given her the opportunity to see Cooper grow up stronger and because it would benefit him in the long run. Amanda teaches Cooper the importance of taking his medicine, even during the hard days when he wants to be like his friends.

Cooper's mom, Amanda, is proud of Cooper, the longest-lived DMP, and have on his side, Cooper's dad, Cooper's grandmother, sending medical consultations, Cooper's brother, Cooper's sister, and Cooper's dog, Bella.

Read Cooper's story

Tabs **Important Safety Information** and **Full Prescribing Information** (including **Patient Information**) for KAUTDECO

KAUTDECO
Carter
Age 10, DMD

For Kristen and Hakeem, sticking to a routine is important.

Kristen Williams is 7 years old. He loves basketball, karate, fishing, and pull-ups.

Read Kristen's story

KAUTDECO
Carter
Age 10, DMD

Carter enjoys diligent sheet taking his KAUTDECO.

Carter's mom, Jessica, is proud of KAUTDECO from the beginning of the opportunity to be the first patient to enroll, by about 1 3 years the DMD.

Read Carter's story

KAUTDECO
Carter
Age 10, DMD

Henry is passionate about his music and his health.

Henry has always been a passion of mine, and he's been a passion of his health. Henry's mom, Jessica, is proud of Henry's dedication to his health.

Read Henry's story

AG content

KAUTDECO
Ryan
Age 17 months, DMD

Grady got an early start with KAUTDECO

Grady's mom, Jessica, is proud of Grady's dedication to his health. Grady's mom, Jessica, is proud of Grady's dedication to his health.

Read Grady's story

KAUTDECO
Ryan
Age 17 months, DMD

Hank strives to be strong and active.

Hank's mom, Jessica, is proud of Hank's dedication to his health. Hank's mom, Jessica, is proud of Hank's dedication to his health.

Read Hank's story

KAUTDECO
Ryan
Age 17 months, DMD

Kaylin finds strength in her support system.

Kaylin's dogs, and I love spending time with Kaylin's family. Kaylin's dogs, Kaylin's family, Kaylin's school, Kaylin's dogs, and I love spending time with Kaylin's family.

Read Kaylin's story

KAUTDECO
Carter
Age 10, DMD

Amanda teaches Cooper the importance of taking his medicine.

Cooper is a 10-year-old with Duchenne MD. He is the youngest and smallest in his class. Cooper's mom, Amanda, knows that he wants to be like his friends and that he can be active but frequent trips into hospitals are hard on his family.

Read Cooper's story

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Age 10, DMD

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Read Kristen's story

KAUTDECO
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Age 10, DMD

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Carter's mom, Jessica, is proud of KAUTDECO from the beginning of the opportunity to be the first patient to enroll, by about 1 3 years the DMD.

Read Carter's story

KAUTDECO
Carter
Age 10, DMD

Henry is passionate about his music and his health.

Henry has always been a passion of mine, and he's been a passion of his health. Henry's mom, Jessica, is proud of Henry's dedication to his health.

Read Henry's story

Videos

Tabs **Important Safety Information** and **Full Prescribing Information**, including **Patient Information**, for KAUTDECO

Watch Now!

How to Take KAUTDECO? Oral Accutane

Learn about KAUTDECO

A Guide to KAUTDECO Patients

Tabs **Important Safety Information** and **Full Prescribing Information**, including **Patient Information**, for KAUTDECO

A Guide to KAUTDECO for Caregivers of Infants

This brochure provides information on KAUTDECO treatment for infants with severe recalcitrant nodular acne ages 1 month to less than 2 years old, and how to give your child KAUTDECO oral suspension.

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FAQs

Tabs **Important Safety Information** and **Full Prescribing Information**, including **Patient Information**, for KAUTDECO

Watch Now!

How does KAUTDECO work?

Learn about KAUTDECO

A Guide to KAUTDECO Patients

Tabs **Important Safety Information** and **Full Prescribing Information**, including **Patient Information**, for KAUTDECO

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Resources

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Stories

Age 5, LEMP

Mouse and Molly's story is inspiring

Every story is unique. KALYDECO brings them together.

"We were excited to get Mouse started and believed it would benefit him in the long run."
— Cooper's mom, Amanda

Hear from the KALYDECO community

Why Brady's Parents Chose KALYDECO

Watch Allison and Chad share why taking KALYDECO was the right choice for their son, Brady.

Read more **Hear from Kathy Satterlee and Patient Advocate Mike Hoskins**
Patient Information for Mike Hoskins

Stacy is passionate about her mom and her health

Stacy's parents have been a passion of mine, and I'm so grateful to be able to help them with their medication.

Read more

Carter says diligent about taking his KALYDECO

Carter's mom shared about taking his KALYDECO. Doing one of my appointments, he was diligent about taking his KALYDECO.

Read more

AE content

Brady got an early start with KALYDECO

Watch Allison and Chad share why taking KALYDECO was the right choice for their son, Brady. 9 months old was the right decision for Brady.

Watch

Kyle Kirkham, Age 21, Utah
Mar 17, 2021
Updated: Mar 17, 2021

Kyle Kirkham finds strength in her support system

Hope is the thing that keeps Kyle Kirkham's outlook with Rheb. Kyle's stepp breakthrough thing to hope grief and life in Utah.

Read More

Karen Fordham, Age 21, Utah
Mar 17, 2021
Updated: Mar 17, 2021

Mock strikes its stay strong and active

"I have enjoyed most of my life with my CF and I have been very active. I love to be outdoor and being active. I'm 21 years old. I'm an Aggie (Utah alum) of Washington.

Read More

Karen Fordham, Age 21, Utah
Mar 17, 2021
Updated: Mar 17, 2021

Karen Fordham, Age 21, Utah, is an Aggie (Utah alum) of Washington.

Read More

Cooper, Age 5, Carter's brother
Mar 17, 2021
Updated: Mar 17, 2021

Amanda teaches Cooper the importance of taking medicine on time

Cooper loves being her brave big brother. He's also an whole program and enjoyed it. He's also a big fan of Mickey Mouse and cute and down his dress.

Read More

Carter, Age 5, Cooper's brother
Mar 17, 2021
Updated: Mar 17, 2021

Carter says diligent about taking his KALYDECO

Carter's mom shared about taking his KALYDECO. Doing one of my appointments, he was diligent about taking his KALYDECO.

Read More

Videos

Video **Important Safety Information** and **Full Prescribing Information** for this video, **Patient Information**, for KALYDECO

Watch Now

How to Take KALYDECO? Oral Granules

Downloadable Resources

Learn about KALYDECO

This brochure provides information on KALYDECO, including what it is, who it is for, how it is taken, and what to expect. For ages 2 years and, and how to give your child KALYDECO oral granules.

View

Descargar Recursos en Español

Learn how to take KALYDECO

A Guide to KALYDECO (Tablets)

This brochure provides information on KALYDECO, including what it is, who it is for, how it is taken, and what to expect. For ages 6 years and, and how to take KALYDECO tablets.

View

FAQs

Tablets and granules

Additional questions about KALYDECO

- How does KALYDECO work?
- Does KALYDECO cure cystic fibrosis (CF)?
- How does KALYDECO work?
- I have 2 copies of the F508del mutation. Why isn't KALYDECO for me?
- What should I tell my doctor before taking KALYDECO?
- What should I avoid while taking KALYDECO?
- What are the possible side effects KALYDECO?
- Why do I need my liver enzymes checked while taking KALYDECO?
- When should I take KALYDECO?
- Why do I need to take KALYDECO with fat-containing food?
- I have additional questions about KALYDECO. What should I do?
- Where can I get my KALYDECO prescription filled?

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used alone or in combination with other medicines (CFTR modulators) for people 2 years and older with cystic fibrosis (CF) who have at least one mutation in the cystic fibrosis transmembrane regulator (CFTR) gene that is responsive to ivacaftor, based on laboratory tests.

Ivacaftor is a medicine that helps the CFTR protein work better. It is not for people with CF who have two copies of the F508del mutation in both genes.

It is not known if KALYDECO is safe and effective in children under 2 months of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- have cataracts or have had cataract operations. KALYDECO may cause cataracts in children. Your doctor will decide if you should have your eyes checked for cataracts before and during treatment with KALYDECO.
- are pregnant or plan to become pregnant. It is not known if KALYDECO passes into breast milk. Do not breastfeed while taking KALYDECO. Women of childbearing age should use an effective birth control.

Tell your doctor about all the medicines you take, including vitamins and herbal supplements. Over-the-counter medicines, vitamins, and herbal supplements could interfere with how KALYDECO works.

Ivacaftor causes, when taken with medicines containing rifamycin, decreased blood levels of ivacaftor. Do not take ivacaftor with medicines containing rifamycin (RIFAMPIN®, or rifampicin).

Cyclosporine causes increases in ivacaftor exposure. Limit the dose of ivacaftor to 150 mg every other day when taking cyclosporine.

Do not take KALYDECO if you are taking:

- strong CYP3A inhibitors (KETOCONAZOLE®, or ketoconazole)
- strong CYP3A inducers (RIFAMPIN®, or rifampicin)
- ketoconazole medicines such as KETOCONAZOLE® (ketoconazole), itraconazole (SPORANOX®), voriconazole (VFEND®), or posaconazole (NOXAFIL®)
- rifamycin medicines such as RIFAMPIN® (rifampicin), rifabutin (MYCOBUTIN®), or rifapentine (PRIFTIN®)
- cyclosporine (SANDIMMUNE®, NEORAL®, or GENGRAF®)

What should I consult with taking KALYDECO?

Tell your doctor if you have bruises in some people after taken. If you have bruising or bleeding, tell your doctor if you have unusual or easy bruising.

Tell your doctor if drink substantially grapefruit juice or eat a lot of grapefruit.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- high liver enzyme levels seeing blood tests. Your doctor will check your liver function before you start KALYDECO and during treatment with KALYDECO.
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year after you are taking KALYDECO

For people who have had high liver enzyme levels in the past, your doctor may decide to stop your treatment with KALYDECO.

Call your doctor right away if you have any of the following symptoms:

- right upper abdominal pain
- jaundice (yellowing of the skin or whites of the eyes)
- dark urine
- unusual tiredness
- loss of appetite

Some common side effects have happened to people who are treated with KALYDECO. Tell your doctor if these provoke or go to the emergency room right away if you have symptoms of an allergic reaction, including:

- rash or hives
- swelling of the face, tongue, or throat
- difficulty breathing or swallowing

Allergic reactions have happened in people who are treated with KALYDECO and ointments resulting KALYDECO. Tell your doctor if you have symptoms of an allergic reaction. Your treatment with KALYDECO may be interrupted.

The most common side effects of KALYDECO include:

- headache
- diarrhea
- stomach pain
- nausea
- rash
- dizziness
- upper respiratory tract infection
- nasal or sinus congestion
- sore throat

Your doctor will ask if you are taking medicines that may cause side effects or interact with KALYDECO. Tell your doctor about all the medicines you take.

Use of KALYDECO in children aged 2 years and older with a gene mutation that is responsive to ivacaftor is based on data from 39 weeks but not beyond weeks.

Please see the full Prescribing Information and Patient Information.

Do you need KALYDECO prescribed drug or not need to be taking KALYDECO?

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Vertex Pharmaceuticals Incorporated

Stories · Videos · Downloadable Resources · FAQs

Resources

Stories · Videos · Downloadable Resources · FAQs

age 6, LADD®

Pediatric patient and parent
Kalydeco® (ivacaftor) 50 mg tablet

Every story is unique. KALYDECO brings them together.

"We were excited to get started and tolerated it would benefit him in the long run."
— Cooper's mom, Amanda

0 / 1:15

Hear from the KALYDECO community

Read Stories
Age 21 Months, SSW2

Brady got an early start with KALYDECO

Brady's Mitzua and Dean share why starting when Brady, at 6 months old, was the right time to start treating his cystic fibrosis (CF).

Read Story

Kaylen Fickenscher
Age 12, CO

For Kaylen and Kaden, stickiness is a common theme

My son Kaden is 7 years old. He loves baseball, karate, fishing, and just being boys.

Read Story

Carter Gibson
Age 4, OH

Carter stays diligent about taking his KALYDECO

I find it ironic that KALYDECO finds me when I was flaring one of my appointments. Not wanting to be diagnosed, I knew I'd be ...

Read Story

AG content

Brady
Age 6 Months, SSW3

Brady got an early start with KALYDECO

Brady's Mitzua and Dean share why, at 6 months old, they chose to start treating his cystic fibrosis (CF).

Watch

Kaylen
Age 12, CO

Kaylen finds strength in her support system

I have 2 dogs, and I love spending time with them. Kaylen's dad, Jeff, and I have been flying airplanes for a lot of years. Jeff is one of the hearts-driven of challenges.

Read Story

Kaden
Age 7, CO

Yeritza GIPTY: Guidance & Patient Assistance Program (GAPAP)

Yeritza's son Kaden is 7 years old. He loves to be his best self for him, and we were ...

Read Story

Carter
Age 4, OH

Amanda teaches Cooper the importance of taking his medicine

Cooper's mom, Amanda, shares why it's so important and rewarding for her to be the first person she and Dean, his dad, ...

Read Story

Kaden
Age 7, CO

For Kaden and Kaden, sticking to a routine is key

My son Kaden is 7 years old. He loves baseball, karate, fishing, and just being boys.

Read Story

Carter
Age 4, OH

Carter stays diligent about taking his KALYDECO

I find it ironic that KALYDECO finds me when I was flaring one of my appointments. Not wanting to be diagnosed, I knew I'd be ...

Read Story

Videos

Learn how to take KALYDECO

Watch

Downloadable Resources

Learn about KALYDECO

This brochure provides information on how KALYDECO works, results for children in clinical trials, 3 ways to use KALYDECO, and how to get ready to start your child on KALYDECO.

View

Documento Resumen en Español

Learn how to take KALYDECO

A Guide to KALYDECO (Tablets)

This guide provides information for parents and caregivers on how to use KALYDECO tablets.

View

FAQs

Tablets and granules · Tablets only · Additional information

What is KALYDECO?

Does KALYDECO treat cystic fibrosis (CF)?

Who is KALYDECO for?

Who should take KALYDECO?

Why do I need to take KALYDECO?

What is cystic fibrosis (CF)?

How should I take KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need to take KALYDECO?

Can I stop taking KALYDECO?

I have additional questions about KALYDECO. Who should I ask?

Where can I get my KALYDECO prescription filled?

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have a gene mutation that causes a specific change in the protein called cystic fibrosis transmembrane regulator (CFTR) gene that affects the function of the CFTR protein.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all your medical conditions, including if you:

- have liver or kidney problems
- have cataracts or have had cataract operations in childhood. Your doctor may need to do a baseline ophthalmic exam before you take KALYDECO.
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. Pregnancy testing should be done in all women who are pregnant. Women who are pregnant should avoid taking KALYDECO unless your doctor decides that it is clearly needed for your health.
- are pregnant and taking ivacaftor-containing medicines, you and your doctor will decide if you should take KALYDECO while you are breastfeeding.

Tell your doctor about all medicines you take, including vitamins and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. In particular, tell your doctor if you take the following:

- the antibiotics rifampin (RIFAMPIN®), rifabutin, rifapentine
- seizure medicines such as phenobarbital, phenytoin, carbamazepine, oxcarbazepine, lacosamide, ezogabine (retigabine), or perampanel
- antifungal medicines such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole, miconazole (LAVIGRO®), or fluconazole (DIFLUCAN®)
- the antibiotics erythromycin or azithromycin
- cardiac medicines such as amiodarone, dronedarone, quinidine, ranolazine, verapamil, diltiazem, or ivabradine
- cyclosporine A
- tacrolimus or sirolimus

Tell your doctor if you have any other medical conditions or are taking any other medicines.

What should I consult with taking KALYDECO?

KALYDECO can cause dizziness in some people who take it. If you experience dizziness, you should not perform tasks requiring alertness, such as operating machinery or driving a car.

Hypersensitivity reactions, including rash, have occurred in people who have taken KALYDECO. If you experience signs and symptoms of a hypersensitivity reaction, you should stop taking KALYDECO and contact your doctor.

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects.

KALYDECO can cause serious side effects. Adults who have taken KALYDECO have experienced a people receiving KALYDECO have had serious liver tests to check your liver.

Before you start KALYDECO treatment, a blood test will be taken to check your liver function.

Your doctor may decide that or blood or difficulty breathing.

Signs headaches or dizziness.

- abdominal (stomach) pain
- diarrhea
- rash
- dizziness

Signs and symptoms of liver problems may include:

- loss of appetite
- nausea or vomiting
- pain, swelling, or tenderness in the upper right part of your abdomen (stomach area)
- jaundice (yellowing of the skin or the whites of the eyes)
- unusual bleeding or bruising
- tiredness
- dark urine (tea-colored)

Serious lung problems have happened in people who are treated with KALYDECO. Tell your doctor if you have any of the following symptoms: cough, wheezing, difficulty breathing, or fever.

Tell your doctor if you have any other side effects while taking KALYDECO.

Tell your doctor if you have any other side effects of KALYDECO. For more information, see the Prescribing Information.

Can your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the Prescribing Information and Patient Information

Talk to your healthcare provider or may

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Resources

Stories · Videos · Downloadable Resources · FAQs

Resources

Hi, I'm Jessica and I'm a proud mom of two from Seattle, WA.

Every story is unique. KALYDECO brings them together.

"I enjoy being outdoors and being active."

"I love my family and friends."

Hear from the KALYDECO community

Stories
Age 21 Months, GERD

Watch Jessica's story

For Kristen and Matthew, whether to breastfeed

My son Matteo is 7 years old. He loves soccer, tennis, fishing, and just being outside.

Read More

Stories
Age 7 Months, Pancreatitis

Watch Kristen's story

Carter shows diligence about taking his KALYDECO

Chris's friend shared KALYDECO from his own. During one of his appointments he asked his doctor if it was the right medicine for Chris.

Read More

Stories
Age 7 Months, GERD

Watch Carter's story

All content

Stories
Age 6 Months, Pancreatitis

Watch Chris's story

Brody got an early start with KALYDECO

Brody's mom, Jessica, and his dad, Jeremy, are from Jersey, PA. KALYDECO at age 2 months gave him and his family a good start.

Read More

Stories
Age 2 Months, GERD

Watch Brody's story

Kaitlin finds strength in her support system

I have 2 dogs, and I love spending time with them and my family. I also like to go to the beach and have a huge part of my life with my family.

Read More

Stories
Age 12 Years, CF

Watch Kaitlin's story

Vertex GPS™ Guidance & Patient Information for KALYDECO

I think heard about KALYDECO would be the best option for her, and we were ready to try something new.

Read More

Stories
Age 7 Years, CF

Watch Carter's story

Annalise teaches Cooper the importance of taking his medicines

Cooper's favorite activities are fishing. We are very proud and excited for him. He has been on KALYDECO for almost 50% and not does his best.

Read More

Stories
Age 10 Years, CF

Watch Cooper's story

For Kristen and Matthew, whether to breastfeed

My son Matteo is 7 years old. He loves soccer, tennis, fishing, and just being outside.

Read More

Stories
Age 7 Years, GERD

Watch Matteo's story

Chris is passionate about his music and his friends

Chris's mom always been a passion of mine, and I know how much he enjoys music, and I wanted to do me.

Read More

Stories
Age 6 Years, Pancreatitis

Watch Chris's story

Brody is passionate about his music and his friends

Brody's mom, Jessica, and his dad, Jeremy, are from Jersey, PA. KALYDECO at age 2 months gave him and his family a good start.

Read More

Stories
Age 2 Months, GERD

Watch Brody's story

Videos

Watch Jessica's story

Watch Kristen's story

Watch Matteo's story

Watch Chris's story

Watch Brody's story

Watch Carter's story

Watch Cooper's story

Watch Kaitlin's story

Watch Annalise's story

Watch Mary's story

Watch Mark's story

Watch Kevin's story

Watch Mark's story

Watch Kevin's story

Watch Mark's story

Watch Kevin

FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

711+3A→G*	F311del	I148T
2789+5G→A*	F311L	I175V
3272-26A→G*	F508C	I807M
3849+10kbC→T*	F508C;S1251N†	I1027T
A120T	F1052V	I1139V
A234D	F1074L	K1060T
A349V	G178E	L206W*
A455E*	G178R*	L320V
A1067T	G194R	L967S
D110E	G314E	L997F
D110H	G551D*	L1480P
D192G	G551S*	M152V
D579G*	G576A	M952I
D924N	G970D	M952T
D1152H* D1152H*	G1069R G1069R	P67L* P67L*
D1270N	G1244E*	Q237E
E56K	G1249R	Q237H
E193K	G1349D*	Q359R
E822K	H939R	Q1291R
E831X*	H1375P	R74W
R75Q	S589N	R117C*
S737F	R117G	S945L*
R117H* S1159F	S977F* R117P	R117L S1159P
R170H	S1251N*	R347H*
S1255P*	R347L	T338I
R352Q*	T1053I	R553Q
V232D	R668C	V562I
R792G	V754M	R933G
V1293G	R1070Q	W1282R
R1070W*	Y1014C	R1162L
Y1032C	R1283M	
S549N*	S549R*	

*Clinical data exists for these mutations. See clinical studies.

†Complex/compound mutations. Most people with CF have 2 CF mutations, 1 on each copy of the CF gene. However, in rare instances, 1 copy of the CF gene can have more than 1 mutation. This is called a compound, or complex, mutation.

Does KALYDECO cure cystic fibrosis (CF)?

How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

I have additional questions about KALYDECO. Who should I talk to?

Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

Does KALYDECO cure cystic fibrosis (CF)?

No, KALYDECO is not a cure for CF.

How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

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FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

Does KALYDECO cure cystic fibrosis (CF)?

How does KALYDECO work?

KALYDECO affects the CFTR protein "gating." KALYDECO helps the "gates" of the CFTR proteins stay open longer, allowing more chloride ions to move into and out of the cells. The movement of chloride ions may help keep a balance of salt and water in the lungs. KALYDECO does not increase the amount of CFTR proteins at the cell surface.

What is known about how KALYDECO works was learned from studies conducted in a laboratory. Keep in mind that results from laboratory studies do not always match how these medicines work in a person. If you have any questions about your treatment, please speak with your healthcare provider.

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

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FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

Does KALYDECO cure cystic fibrosis (CF)?

How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

KALYDECO is not indicated for people with 2 copies of the F508del mutation.

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

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FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

Does KALYDECO cure cystic fibrosis (CF)?

How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

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FAQs

Tablets and granules | Additional tablets info | Additional granules info

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I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve.

Avoid food or drink containing grapefruit while you are taking KALYDECO.

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

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FAQs

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What is KALYDECO?

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How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)**, which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

I have additional questions about KALYDECO. Who should I talk to?

Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

What is KALYDECO?

Does KALYDECO cure cystic fibrosis (CF)?

How does KALYDECO work?

I have 2 copies of the F508del mutation. Why isn't KALYDECO right for me?

What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

High liver enzymes in the blood have happened in people receiving KALYDECO.

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

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What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Take KALYDECO orally every 12 hours with fat-containing food unless otherwise directed by your healthcare provider.

Please see full dosing information.

Why do I need to take KALYDECO with fat-containing food?

I have additional questions about KALYDECO. Who should I talk to?

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FAQs

Tablets and granules | Additional tablets info | Additional granules info

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What should I tell my doctor before taking KALYDECO?

What should I avoid while taking KALYDECO?

What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

KALYDECO should be taken with fat-containing food because fat-containing food helps the body absorb KALYDECO better.

I have additional questions about KALYDECO. Who should I talk to?

Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

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What are the possible side effects of KALYDECO?

Why do I need my liver enzymes checked every 3 months?

When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

I have additional questions about KALYDECO. Who should I talk to?

If you have questions about KALYDECO, please talk to your doctor. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.

Where can I get my KALYDECO prescription filled?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

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When should I take KALYDECO?

Why do I need to take KALYDECO with fat-containing food?

I have additional questions about KALYDECO. Who should I talk to?

Where can I get my KALYDECO prescription filled?

Prescriptions for KALYDECO can only be filled at authorized specialty pharmacies. If you'd like to see a list of specialty pharmacies and specialty distributors, **click here**. Based on your health plan, there may be restrictions on which pharmacies you can use.

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

You may cut along the dotted line to separate your doses from the blister card.

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

KALYDECO should be stored at 68°F to 77°F (20°C to 25°C).

Do not use KALYDECO after the expiration date on the package.

Keep KALYDECO and all medicines out of the reach of children.

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

For people 6 years and older, KALYDECO tablets are supplied as light blue, film-coated, capsule-shaped tablets containing 150 mg of ivacaftor. Each tablet is printed with the characters "V 150" on one side and plain on the other.

Not actual size.

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

If you miss a dose of KALYDECO and it is **within 6 hours** of when you usually take it, take the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

If you miss a dose and it is **more than 6 hours** after the time you usually take it, **skip that dose only** and take the next dose with fat-containing food when you usually take it.

Do **not** take 2 doses at the same time to make up for a missed dose.

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

Can I separate the doses on the blister cards?

How should I store KALYDECO tablets?

What do KALYDECO tablets look like?

What if I miss a dose of KALYDECO?

I have additional questions about KALYDECO. Who should I talk to?

If you have questions about KALYDECO, please talk to your healthcare provider. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

The granules should be taken within 1 hour of mixing with soft food or liquid. Make sure all medicine is taken.

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

KALYDECO should be stored at room temperature between 68°F to 77°F (20°C to 25°C).

Do not use KALYDECO after the expiration date on the package.

Keep KALYDECO and all medicines out of the reach of children.

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

KALYDECO is supplied as oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg packets) for people age 1 month to less than 6 years.

Not actual size.

Not actual size.

Not actual size.

Not actual size.

Not actual size.

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

The recommended dose of KALYDECO oral granules for children age 1 month to less than 6 years old is based on weight.

The recommended dose of KALYDECO oral granules for children age **1 month to less than 2 months old** who weigh **3 kg (~7 lb) or more** is one 5.8-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 11.6 mg.

The recommended dose of KALYDECO oral granules for children age **2 months to less than 4 months old** who weigh **3 kg (~7 lb) or more** is one 13.4-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 26.8 mg.

The recommended dose of KALYDECO oral granules for children age **4 months to less than 6 months old** who weigh **5 kg (~11 lb) or more** is one 25-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 50 mg.

Children who weigh **5 kg to less than 7 kg (~11 lb to less than ~15 lb)** should take one 25-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 50 mg.

Children who weigh **7 kg to less than 14 kg (~15 lb to less than ~31 lb)** should take one 50-mg packet mixed with 1 teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 100 mg.

Children who weigh **14 kg (~31 lb) or more** should take one 75-mg packet mixed with one teaspoon (5 mL) of soft food or liquid every 12 hours for a total daily dose of 150 mg.

Give your loved one fat-containing food just before or just after the dose of KALYDECO granules. This helps the body absorb KALYDECO better.

Your healthcare provider may give you different instructions on how much KALYDECO to give your loved one and when you should give it.

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

  Yes, KALYDECO oral granules can be mixed with 1 teaspoon (5 mL) of breast milk or prepared infant formula at or below room temperature. Be sure that the entire mixture is taken by your loved one within 1 hour. Remember you should always give your loved one KALYDECO with a fat-containing food.
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?

  If your loved one misses a dose of KALYDECO and it is **within 6 hours** of when it is usually given, give the dose of KALYDECO as prescribed with fat-containing food as soon as possible.

  If your loved one misses a dose and it is **more than 6 hours** after the time the dose is usually given, **skip that dose only** and give the next dose with fat-containing food when it is usually given.

  Do **not** give 2 doses at the same time to make up for a missed dose.
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

  Yes, you can mix KALYDECO granules with fat-containing food, for example, 1 teaspoon (5 mL) of whole-milk yogurt or milk, to give to your loved one. But your loved one should still eat fat-containing food just before or after taking the mixture.
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Yes, breast milk and prepared infant formula qualify as fat-containing food.

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

- After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?
- How should I store KALYDECO oral granules?
- How are KALYDECO oral granules packaged?
- What is the recommended dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in breast milk or prepared infant formula?
- What if my loved one misses a dose of KALYDECO oral granules?
- Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?
- Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?
- Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

  The granules should be mixed with soft food or liquid at room temperature or below.
- Can my loved one swallow the granules without mixing them in soft food or liquid?
- Do the granules have a taste?
- My loved one spit up their dose of KALYDECO oral granules. What should I do?
- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
- Are the packets childproof?
- When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?
- Will my loved one require a new prescription when changing strengths or dosage forms?
- I have additional questions about KALYDECO. Who should I talk to?

FAQs

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

The entire contents of each packet should be mixed with 1 teaspoon (5 mL) of age-appropriate soft food or liquid. The mixture should be given within 1 hour of being mixed. Make sure all medicine is taken.

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

The granule formulation is sweetened but unflavored.

My loved one spit up their dose of KALYDECO oral granules. What should I do?

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

I have additional questions about KALYDECO. Who should I talk to?

FAQs

Tablets and granules | Additional tablets info | Additional granules info

After the granules are mixed in soft food or liquid, how quickly does my loved one need to take the medicine?

How should I store KALYDECO oral granules?

How are KALYDECO oral granules packaged?

What is the recommended dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in breast milk or prepared infant formula?

What if my loved one misses a dose of KALYDECO oral granules?

Can I mix KALYDECO oral granules in soft food or liquid that contains fat? If so, do I still need to give fat-containing food to my loved one?

Do breast milk and prepared infant formula qualify as fat-containing foods that my loved one can take with KALYDECO?

Does the temperature of the food that I mix with KALYDECO oral granules matter? Can I mix oral granules in breast milk or prepared infant formula that I've warmed?

Can my loved one swallow the granules without mixing them in soft food or liquid?

Do the granules have a taste?

My loved one spit up their dose of KALYDECO oral granules. What should I do?

You should contact your loved one's healthcare provider to discuss this. Your pharmacist may also be a good resource.

If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

Will my loved one require a new prescription when changing strengths or dosage forms?

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- If my loved one is napping when it is time for KALYDECO oral granules, should I wait until they're awake to administer them?

  You should give your loved one KALYDECO oral granules every 12 hours or as prescribed by your loved one's healthcare provider.
- Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?
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  No, granules should be kept in the foil packet until they are ready to be used.
- Are the packets childproof?
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Should the granules be removed from the foil packet and stored elsewhere (for example, a pillbox)?

Are the packets childproof?

The packets are child-resistant.

When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

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When should my loved one transition from taking KALYDECO oral granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) to KALYDECO tablets (150-mg)?

KALYDECO granules (5.8-mg, 13.4-mg, 25-mg, 50-mg, or 75-mg) are for use in children who are 1 month to less than 6 years of age, while KALYDECO tablets (150-mg) are for use in children age 6 years and older. You and your loved one's healthcare provider should discuss when to transition your loved one to KALYDECO tablets.

Will my loved one require a new prescription when changing strengths or dosage forms?

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- Will my loved one require a new prescription when changing strengths or dosage forms?

  Yes, your loved one will need a new prescription when they change to a new strength or dosage form.
- I have additional questions about KALYDECO. Who should I talk to?

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- I have additional questions about KALYDECO. Who should I talk to?

  If you have questions about KALYDECO, please talk to your doctor. You can also find information about KALYDECO in the **full Prescribing Information**, including **Patient Information**.

Resources

Vertex GPS™ is here to help you get there

Wherever life with cystic fibrosis (CF) takes you, **Vertex GPS™ Guidance & Patient Support** is here to help you get there. Vertex GPS offers personalized, one-on-one support to help you start and stay on track. Once you're enrolled, you'll be assigned a dedicated Support Specialist who will be with you every step of the way.

Here are just some of the ways your Support Specialist can help:

Get you started on treatment by verifying your coverage and out-of-pocket costs with your **insurance company**. They'll also connect you with **healthcare providers** to discuss any requirements or questions your insurance company may have while determining coverage.

Help you explore financial assistance options, regardless of your insurance coverage. And if you have commercial insurance, the Vertex GPS Co-pay Assistance Program may be able to lower your co-pay to as little as $0 per fill.*

*Eligibility restrictions and limitations apply. Annual assistance is limited to a maximum of $20,000.

Keep you on track with your treatment by coordinating shipments with your **specialty pharmacy** and reminding you when it's time to refill your Vertex medicine. And if your daily routine changes, they can help you pre-plan refills, ship your treatment to a new address, and share tips to help you stay motivated.

Not enrolled in Vertex GPS?

If you have been prescribed a Vertex medicine treatment, ask your healthcare provider to complete an enrollment form for you.

Already enrolled?

If you are currently enrolled in GPS, you can call or text your Support Specialist at **1-877-752-5933 (press 2 when calling)**, Monday through Friday, from 8:30 AM to 7 PM ET.

Personalized support—for whatever's up next

Learn more about GPS and the support resources available at VertexGPS.com.

Discover more

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an individual CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO® or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROL®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machinery until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people who took KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdomen) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Important Safety Information & Indication

What is KALYDECO® (ivacaftor)?

KALYDECO is a prescription medicine used for the treatment of cystic fibrosis (CF) in people aged 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to KALYDECO.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if KALYDECO is safe and effective in children under 1 month of age.

IMPORTANT SAFETY INFORMATION

Before taking KALYDECO, tell your doctor about all of your medical conditions, including if you:

- have liver or kidney problems
- are allergic to KALYDECO or any ingredients in KALYDECO. See the Patient Information for a list of ingredients
- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
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You may be able to find what you're looking for on the KALYDECO® home page.

Back to home

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Site Map

Home

About KALYDECO
- How KALYDECO Works
- Who KALYDECO Is For
- KALYDECO Results

Safety & Side Effects
- Safety & Side Effects

Taking KALYDECO
- How to Take KALYDECO
- Fat-Containing Food Ideas

Resources
- Stories, Videos, and Downloads
- FAQs
- Vertex GPS™: Patient Support Program
- Recursos En Español

Important Safety Information
- Important Safety Information

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- are pregnant or plan to become pregnant. It is not known if KALYDECO will harm your unborn baby. You and your doctor should decide if you will take KALYDECO while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if KALYDECO passes into your breast milk. You and your doctor should decide if you will take KALYDECO while you are breastfeeding

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

KALYDECO may affect the way other medicines work, and other medicines may affect how KALYDECO works. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- the antibiotics rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETROL®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort
- antifungal medicines such as ketoconazole, itraconazole (SPORANOX®), posaconazole (NOXAFIL®), voriconazole (VFEND®), or fluconazole (DIFLUCAN®)
- antibiotics such as telithromycin, clarithromycin (BIAXIN®), or erythromycin (ERY-TAB®)

What should I avoid while taking KALYDECO?

- KALYDECO can cause dizziness in some people who take it. If you experience dizziness, do not drive or operate machines until symptoms improve
- Avoid food or drink containing grapefruit while you are taking KALYDECO

What are the possible side effects of KALYDECO?

KALYDECO can cause serious side effects, including:

- **High liver enzymes in the blood,** which have happened in people receiving KALYDECO. Your doctor will do blood tests to check your liver:
  - before you start KALYDECO
  - every 3 months during your first year of taking KALYDECO
  - every year while you are taking KALYDECO

For people who have had high liver enzymes in the past, your doctor may do blood tests to check the liver more often.

Call your doctor right away if you have any of the following symptoms of liver problems:

  - pain or discomfort in the upper right stomach (abdominal) area
  - yellowing of your skin or the white part of your eyes
  - loss of appetite
  - nausea or vomiting
  - dark, amber-colored urine
- **Serious allergic reactions** have happened to people who are treated with KALYDECO. Call your healthcare provider or go to the emergency room right away if you have symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
  - rash or hives
  - tightness of the chest or throat or difficulty breathing
  - light-headedness or dizziness
- **Abnormality of the eye lens (cataract),** which has happened in some children and adolescents receiving KALYDECO. Your doctor should perform eye examinations before and during treatment with KALYDECO to look for cataracts.

The most common side effects of KALYDECO include:

- headache
- upper respiratory tract infection (common cold), including:
  - sore throat
  - nasal or sinus congestion
  - runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- nausea
- dizziness

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of KALYDECO. For more information, ask your doctor or pharmacist.

Use of KALYDECO in children aged 1 month to less than 6 months born from a pregnancy lasting (gestational age) less than 37 weeks has not been evaluated.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For further information, please see **full Prescribing Information**, including **Patient Information**.

People with CF pictured may or may not be taking KALYDECO.

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Are you a US healthcare professional?

Yes No

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