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2. Kalydeco

Kalydeco

Generic name: [ivacaftor](#) [EYE-va-KAF-tor]

Drug class: [CFTR potentiators](#)

Medically reviewed by [Judith Stewart, BPharm](#). Last updated on Sep 28, 2023.

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What is Kalydeco?

Kalydeco is used to treat [cystic fibrosis](#) in adults and children who are at least 1 month old and weigh at least 6 pounds (3 kilograms).

Kalydeco tablets can be used in children aged 6 years and older. Kalydeco granules can be used in children aged 1 month to under 6 years old.

Cystic fibrosis is an inborn disease that causes problems with breathing, digestion, and reproduction) in adults and children 1 month of age and older.

Kalydeco should be used only in people with a specific gene mutation related to cystic fibrosis. Your doctor may order a blood test to help decide if this medication is right for you.

Kalydeco belongs to a class of medications called cystic fibrosis transmembrane conductance regulator (CFTR) potentiators. Ivacaftor works by improving the function of a protein in the body to decrease the build-up of thick mucus in the lungs and improving other symptoms of cystic fibrosis.

Kalydeco side effects

Get emergency medical help if you have **signs of an allergic reaction to Kalydeco**: hives, difficult breathing, swelling of your face, lips, tongue, or throat.

Kalydeco may cause serious side effects. Call your doctor at once if you have:

- blurred vision, eye pain or redness, seeing halos around lights;
- [low blood sugar](#)--[headache](#), hunger, weakness, [sweating](#), confusion, irritability, dizziness, [fast heart rate](#), or feeling jittery; or
- **liver problems** - loss of appetite, [nausea](#), [vomiting](#), stomach pain (upper right side), tiredness, [itching](#), dark urine, clay-colored stools, [jaundice](#) (yellowing of the skin or eyes).

Common Kalydeco side effects may include:

- muscle or [joint pain](#);
- dizziness;
- [rash](#), acne;
- headache;
- mouth pain;
- stomach pain, nausea, [diarrhea](#); or
- [cold symptoms](#) such as stuffy nose, sneezing, runny nose, [sore throat](#).

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Kalydeco side effects](#) (more detail)

Related/similar drugs

Zithromax

Zithromax (azithromycin) treats infections caused by bacteria, such as respiratory infections, skin ...

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7.1 / 10

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Warnings

Before you take Kalydeco, tell your doctor if you have liver or kidney disease.

Kalydeco should be taken with a food that contains fat, such as butter, peanut butter, eggs, cheese pizza, or whole-milk dairy products such as whole milk, cheese, and yogurt. Follow your doctor's instructions very carefully.

Grapefruit, grapefruit juice, and Seville oranges may interact with Kalydeco and lead to unwanted effects. Discuss the use of grapefruit and orange products with your doctor.

To be sure Kalydeco is not causing harmful effects, your liver function will need to be checked with frequent blood tests. Visit your doctor regularly.

There are many other drugs that can interact with ivacaftor. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor. Keep a list of all your medicines and show it to any healthcare provider who treats you.

Before taking this medicine

You should not be treated with Kalydeco if you are allergic to ivacaftor.

To make sure Kalydeco is safe for you, tell your doctor if you have ever had:

- liver or kidney disease.

It is not known if ivacaftor will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

Ask a doctor if it is safe to breastfeed while using Kalydeco.

i [Kalydeco pregnancy and breastfeeding warnings](#) (more detail)

How should I take Kalydeco?

Take Kalydeco exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Take Kalydeco with food that contains fat, such as eggs, milk products such as whole milk, cheese, yogurt, breast milk or infant formula. Follow your doctor's instructions carefully.

Swallow the tablet whole and do not crush, chew, or break it.

Mix the Kalydeco granules with 1 teaspoon of soft food such as pureed fruits or vegetables, yogurt, applesauce, water, breast milk, infant formula, milk, or juice. Mix only 1 dose at a time and use within 1 hour after mixing. Feed the child a high-fat food after or before giving the granule mixture.

Take Kalydeco at evenly spaced intervals every 12 hours.

Doses are based on weight in children. Your child's dose may change if the child gains or loses weight.

You will need frequent blood tests to check your liver function.

Your child may need frequent vision exams.

Store at room temperature away from moisture and heat. Keep the medicine in the original packaging.

Dosing information

Usual Adult Dose for Cystic Fibrosis:

150 mg orally every 12 hours with fat containing food

Comments:

- Examples of fat-containing food include: eggs, butter, peanut butter, cheese pizza, and whole milk dairy products.
- If the patient's genotype is unknown, an approved CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

Uses:

- For the treatment of cystic fibrosis in patients having one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.

Usual Pediatric Dose for Cystic Fibrosis:

Oral Granules:

Age: 4 months to less than 6 months:

Weight: 5 kg or greater: 25 mg orally every 12 hours

-Use is not recommended in the presence of hepatic impairment or in those taking concomitant moderate or strong CYP450 3A inhibitors

Age: 6 months or older:

Weight: 5 to less than 7 kg: 25 mg orally every 12 hours

Weight: 7 to less than 14 kg: 50 mg orally every 12 hours

Weight: 14 kg or greater: 75 mg orally every 12 hours

Oral Tablet:

Age: 6 years and older: 150 mg orally every 12 hours

Comments:

-Doses should be taken just before or after fat-containing food; examples of fat-containing food include: eggs, butter, peanut butter, cheese pizza, and whole milk dairy products.

-Dose adjustments are recommended for patients 6 months or older with hepatic impairment and/or taking concomitant moderate or strong CYP450 3A inhibitors.

-If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

Uses:

-For the treatment of cystic fibrosis in patients 4 months or older having one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.

 [Detailed Kalydeco dosage information](#)

What happens if I miss a dose?

Take the medicine as soon as you can, with a fatty meal, but skip the missed dose if you are more than 6 hours late for the dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking Kalydeco?

Avoid driving or hazardous activity until you know how Kalydeco will affect you. Dizziness or [drowsiness](#) can cause falls, accidents, or severe injuries.

Grapefruit may interact with ivacaftor and cause side effects. Avoid consuming grapefruit products.

What other drugs will affect Kalydeco?

Sometimes it is not safe to use certain medicines at the same time. Some drugs can affect your blood levels of other drugs you use, which may increase side effects or make the medicines less effective.

Tell your doctor about all your other medicines, especially:

- [St. John's wort](#);
- seizure medicine such as [carbamazepine](#), [phenobarbital](#), or [phenytoin](#);
- **an antibiotic** - [clarithromycin](#), [erythromycin](#), [telithromycin](#), [rifabutin](#), [rifampin](#); or
- **antifungal medicine** - [fluconazole](#), [itraconazole](#), [ketoconazole](#), [posaconazole](#), [voriconazole](#).

This list is not complete. Other drugs may interact with ivacaftor, including prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Not all possible drug interactions are listed here.

 [Kalydeco drug interactions](#) (more detail)

Does Kalydeco interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

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Add

Ingredients

Active ingredient: ivacaftor

Ivacaftor tablets:

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The tablet film coat contains: carnauba wax, FD&C Blue #2, PEG 3350, polyvinyl alcohol, talc, and titanium dioxide.

The printing ink contains: ammonium hydroxide, iron oxide black, propylene glycol, and shellac.

Ivacaftor oral granules:

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sucralose, and sodium lauryl sulfate.

Manufacturer

Manufactured for: Vertex Pharmaceuticals Incorporated, 50 Northern Avenue, Boston, MA 02210, USA.

Popular FAQ

How does Kalydeco work?



What is an orphan drug?



More FAQ

- [What is the difference between Symdeko and Orkambi?](#)
- [What is the difference between Symdeko and Kalydeco?](#)

References

1. [Kalydeco Product Label](#)

More about Kalydeco (ivacaftor)

- [Check interactions](#)
- [Compare alternatives](#)
- [Pricing & coupons](#)
- [Reviews \(1\)](#)
- [Drug images](#)
- [Side effects](#)
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- [During pregnancy](#)
- [FDA approval history](#)
- [Drug class: CFTR potentiators](#)
- [Breastfeeding](#)

Professional resources

- [Kalydeco prescribing information](#)
- [Ivacaftor \(AHFS Monograph\)](#)

Related treatment guides

- [Cystic Fibrosis](#)

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Kalydeco only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2012



User Reviews & Ratings

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Images

[Kalydeco 150 mg \(V 150\)](#)

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