



Your Guide to Treatment and Treatment Diary

Starting and staying on course with Kisqali®▼ (ribociclib)

This booklet is not a substitute for the Patient Information Leaflet (PIL) which is provided with the medicine – for further information on symptoms/side effects, please speak with your cancer care team or refer to the PIL which is included in the Kisqali pack.

How to report side effects can be found on page 36 of this booklet.



About this booklet

This booklet is intended for use by patients who have been prescribed Kisqali (kis-KAH-lee) in combination with an **aromatase inhibitor** (AI) (such as letrozole, anastrozole or exemestane).

Kisqali is sometimes called by its generic name: ribociclib. Your doctor, nurse or pharmacist may have used the name ribociclib when talking to you. Kisqali and ribociclib are different names for the same medicine.

This booklet will help inform you about starting Kisqali and keeping your treatment on course. It was created with help from nursing professionals and has been reviewed by a patient reading group.

If you have any questions after reading this booklet, please ask your doctor or nurse. Be open with them about any concerns you have about your treatment or your health. Communicating with your doctor or nurse can help you to better understand your treatment.



Inside this booklet

Before starting treatment

- Who is this treatment for?
- How does this treatment work?
- Before you start your Kisqali treatment

While taking your treatment

- How do I take my treatment?
- What tests will I have?
- What side effects might I experience?
- Tips to help you manage side effects
- Dose interruptions and modifications

Tracking your treatment

- Your appointment tracker
- Your treatment diary

Finding support

- Finding the support you need
- Reporting symptoms/side effects



Not sure what something means? The glossary can help. It has definitions for many of the terms used in this booklet. On the following pages, glossary words are **in bold** the first time they appear.



Who is this treatment for?

You have been prescribed Kisgali because:

- You have locally advanced or metastatic breast cancer (sometimes also called advanced or secondary breast cancer)
- Your breast cancer is a type called HR-positive/HER2-negative (HR+/HER2-)
- You have gone through menopause (this may have been artificially induced or have taken place naturally)

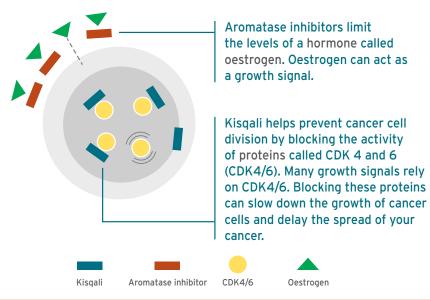


How does this treatment work?

It is normal for many kinds of cells in the body to divide and produce new cells. To do this, they rely on growth signals in the body. Sometimes these signals may tell cells to divide too quickly. This can lead to cancer.

One of the goals of cancer treatment is to slow down the speed cancer cells are dividing at - this can delay growth and spread of your cancer. Kisqali is a type of targeted treatment called a CDK4/6 inhibitor which is taken in combination with an aromatase inhibitor. Aromatase inhibitors are a type of treatment called **hormone therapy** or **endocrine therapy**.

Treatment with Kisqali + an aromatase inhibitor



Both treatments work together to delay the growth of cancer



Before you start your Kisqali treatment

Things you should know



Kisqali is an oral tablet. It is taken with another type of oral medicine called an aromatase inhibitor



You may have concerns about **side effects**, these are discussed further on page 12. In a large clinical trial, the side effects from taking Kisqali in combination with an aromatase inhibitor were mostly mild to moderate and could usually be managed. In some patients some serious side effects also occurred.



You will have some medical tests to check if you are ready to start treatment

Remind your doctor or nurse if you:

- Have a fever, sore throat, or mouth ulcers due to infections (signs of a low level of white blood cells)
- Have any problems with your liver or have previously had any type of liver disease
- Have or have had heart disorders or heart rhythm disorders, such as an irregular heartbeat. This includes QT interval prolongation where the heart takes longer than normal to contract and refill with blood which can affect the heart rhythm
- Have or have had low levels of potassium, magnesium, calcium, or phosphorus in your blood
- Are allergic to peanuts or soya
- Are taking any other medicines or supplements





How do I take my treatment?

Your treatment is taken in a 28-day cycle. This is a treatment you continue to take until your doctor or nurse advises you to stop

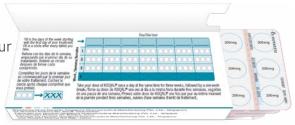
RECOMMENDED 4-WEEK DOSING SCHEDULE (28-DAY CYCLE)

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	
Kisqali 600 mg (3 tablets of 200 mg) once daily					
21 consecutive days of treatment, followed by 7 days off treatment	\bigcirc	\smile	\smile	X	
Aromatase inhibitor Once daily, every day	\bigcirc	⊘	⊘	⊘	

- Your doctor or nurse will tell you the doses you should take for each of your treatments and when you should take them
- Do not change your treatment dose or schedule without talking to your doctor or nurse
- Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect

Track your treatment on the Kisqali package

 Use the dosing calendar on the tablet box to keep track of your treatment each day



Kisqali + an aromatase inhibitor is taken in a 28-day cycle.

Take Kisqali on days 1 to 21 of the 28-day cycle and the

aromatase inhibitor for the entire 28-day cycle



Take your tablets at the same time each day, preferably in the morning. You can take your treatment with or without food



Tablets should be swallowed whole (tablets should not be chewed, crushed, or split prior to swallowing). Do not take any tablet that is broken, cracked, or otherwise not intact, please contact your doctor or nurse for advice if this happens



Avoid pomegranates, pomegranate juice, grapefruits, and grapefruit juice while taking your treatment as these foods may alter the effectiveness of the treatment



If you vomit after taking a dose or forget a dose:

- Skip the missed dose that day
- Take the next dose at your usual time
- Do not take a double dose to make up for a forgotten dose



If you accidentally take too many tablets please contact your doctor or nurse, acute oncology department or any emergency phone number for advice straight away



What tests will I have?

Your doctor or nurse will do all they can to help you with your experience on this treatment. One way they do this is by using medical tests to monitor your health.

Tests to help you get the most out of treatment

You will have had certain tests before starting treatment. You will continue to have these tests during treatment to help your doctor or nurse check for side effects. Tests most often occur during the first 6 months of treatment. These will include:



Blood tests, to check your liver function and to measure the levels of certain blood cells and **electrolytes** (potassium, magnesium, calcium, or phosphorus) in your blood



Electrocardiograms (ECGs), to check the electrical activity of your heart

Monitoring can help identify possible side effects and keep your treatment on course

Appointment dates

The recommended test schedule during your first 2 cycles of treatment is below.

BEFORE TREATMENT	BLOOD TEST	€ ECG
You will receive these tests before starting treatment	\bigcirc	\bigcirc
CYCLE 1	BLOOD TEST	ECG ECG
Around day 14 of the 1st 28-day cycle	\bigcirc	\bigcirc
CYCLE 2	BLOOD TEST	ECG
Around day 1 of the 2nd 28-day cycle	\bigcirc	\bigcirc
Around day 14 of the 2nd 28-day cycle	\bigcirc	Only if your doctor or nurse requires

Blood tests are also recommended at the start of cycles 3, 4, 5, and 6. If your doctor or nurse thinks it's needed, you may continue to have blood tests and ECGs throughout treatment.

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What side effects might I experience?

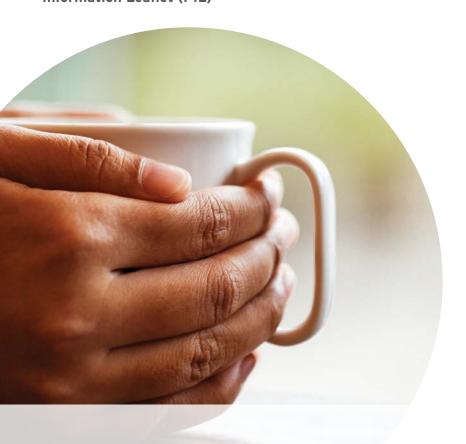
The majority of side effects reported have been mild to moderate

- The most common side effects of treatment are:
 - Low white blood cell counts
- Feeling weak
- Nausea and/or vomiting
- Feeling tired

Diarrhoea

Hair thinning/loss

For more information on side effects, please see the Patient Information Leaflet (PIL)



Some side effects seen with Kisqali may be serious

The medical tests you will have can help your healthcare professional check for these side effects. Based on the results of these tests, your healthcare professional may interrupt or reduce your dose of Kisqali. This will allow your body to recover. If the side effect doesn't go away after interrupting or reducing the dose, your healthcare professional may also decide to stop treatment with Kisqali permanently.

Some serious side effects also have symptoms you can watch for.

If you experience any of the symptoms below, tell your healthcare professional right away

- Low white blood cell counts (neutropenia) can occur and your doctor will monitor for this with blood tests. It is important to tell your nurse or doctor straight away if you feel feverish or have chills
- **Liver problems** can occur. It is important to tell your nurse or doctor straight away if you get itchy, yellow skin or yellowing of the whites of your eye; nausea or vomiting; loss of appetite; pain in the upper right side of your stomach area (abdomen); and dark or brown urine
- QT interval prolongation, which can affect the heart rhythm, does not usually cause symptoms. It can cause people to faint or feel faint, particularly if exercising or if stressed. If you experience this it is important to tell your nurse or doctor straight away

If you have side effects of any kind, it is important to tell your doctor or nurse, as they may be able to help you manage them



Tips to help you manage side effects



Tips to help if you have nausea and vomiting

- Try taking your medicine with food and not on an empty stomach
- Eat frequent, small meals and have a snack at bedtime
- Drink clear fluids (preferably served cold) to prevent dehydration and avoid alcohol
- Avoid certain foods that may make nausea worse, such as spicy and fatty foods, and those high in sugar
- Food or drink containing ginger or peppermint can help reduce nausea, try ginger tea or ginger biscuits or peppermints or peppermint tea
- Slowly sipping a fizzy drink is a popular remedy for feeling sick, try mineral water, ginger ale or lemonade



Tips to help if you have diarrhoea

- Eat frequent, small meals:
- Made from light foods such as dairy produce, white fish, poultry, well-cooked eggs, white bread, pasta or rice
- Eat less fibre (cereals, raw fruits and vegetables) until the diarrhoea improves
- Avoid greasy, fatty foods such as chips and beefburgers, and spicy foods like chilli peppers
- As diarrhoea starts to improve, add foods low in fibre to your diet, such as bananas, rice, and dry toast
- Drink up to two litres of clear fluids a day to prevent dehydration



Tips to help if you have fatigue

- Manage fatigue with rest and regular exercise and spread household tasks over the week
- Pace activities throughout the day
- Try and get at least 8 hours of sleep each night
- Take short naps
- Eat a balanced diet
- If you have children, explain that you're feeling tired.
 Plan activities where you can sit down while spending time with them



Tips to help if you have hair thinning or loss

- Be gentle when brushing and washing your hair; hair loss might be somewhat reduced by avoiding too much brushing or pulling
- You may wish to wear a hat to protect your scalp from the sun
- Use gentle hair products and avoid colouring, perming or relaxing
- Avoid using hairdryers, straighteners or hot rollers

Always tell your doctor or nurse if you experience any side effects or need help managing them



Dose interruptions and modifications

As with other cancer treatments, your doctor or nurse may adjust your Kisqali dose during treatment. This is to help find the dose that is effective but limits the number and severity of side effects. A change in dose most often happens during the first few months of treatment.

Dose modifications are typically done in one of two ways

Do not adjust your dose or stop taking your medication unless directed by your doctor or nurse

A dose interruption:

 This is when your doctor or nurse asks you to stop taking Kisqali for a period of time. You will still take your aromatase inhibitor each day unless your doctor or nurse asks you not to

A dose reduction:

 This is when your doctor or nurse asks you to take fewer tablets of Kisqali each day

Before you restart Kisqali after an interruption, ask your doctor or nurse:

- When you should start taking Kisqali again
- Whether you should finish your current pack or start a new one
- How many Kisqali tablets you should take each day

Kisqali tablets come in one strength

This means that your doctor or nurse can adjust your dose simply by changing the number of tablets you take each day. If your doctor or nurse lowers your dose, you will be able to continue treatment with the treatment pack you already have, rather than waiting for a new prescription.

Tracking your treatment

Use your appointment tracker and treatment diary to help you to stay on course with your treatment.





Your appointment tracker

Your doctor or nurse may refer to your treatment in cycles, one cycle with Kisqali and aromatase inhibitor lasts for 28 days and involves taking Kisqali for the first 21 days and the aromatase inhibitor for the entire 28 days.

The chart below can help you keep track of your test appointments during the first 2 months of your treatment. Fill in the date and time of each appointment with your doctor or nurse to help you remember.

BEFORE TREATMENT	BLOOD TEST	ECG
You may receive these tests before starting treatment	Date: Time:	Date: Time:
CYCLE 1	BLOOD TEST	ECG
You may have a blood test and an ECG around day 14	Date: Time:	Date: Time:
CYCLE 2	BLOOD TEST	ECG
You may have a blood test and an ECG around day 1	Date: Time:	Date: Time:
You may also have a blood test around day 14*	Date: Time:	Date: Time:

^{*}You will only have an ECG on day 14 of cycle 2 if your doctor or nurse requires it

The above tests are recommended for all patients starting on Kisqali + an aromatase inhibitor. However, if your doctor or nurse thinks it's needed, you may continue to have blood tests and ECGs throughout treatment.

Your treatment diary

The recommended starting dose of Kisqali is 600 mg every day (3 tablets of 200 mg). Your doctor or nurse will also prescribe an aromatase inhibitor (such as letrozole, anastrozole or exemestane) that you should take in combination with Kisqali.

- Take Kisqali on days 1 to 21 of a 28-day cycle
- Take your aromatase inhibitor once daily throughout the 28-day cycle

Using your diary

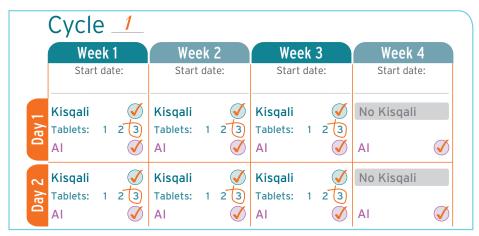
• Fill in CYCLE with which 28-day cycle you are on, one Kisqali + aromatase inhibitor cycle lasts for 28 days. Fill in your start date for each week of the cycle

On the days when you take Kisqali:

- Tick your Kisqali box to show you have taken your Kisqali dose that day
- Circle the number which represents the number of Kisqali tablets you have taken that day
- Tick your AROMATASE INHIBITOR box to show you have taken your aromatase inhibitor daily dose

On the days when you do NOT take Kisqali:

 Tick your AROMATASE INHIBITOR (AI) box to show you have taken your aromatase inhibitor daily dose



Do not adjust your dose or stop taking your medication unless directed by your doctor or nurse



	We	ek 1	Wee	ek i	2	Wee	k:	3	Week 4	
	Start	t date:	Start	dat	:e:	Start (dat	te:	Start date:	
Day 1	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 2	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets:	1	2 3	No Kisqali	
Day 3	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets:	1	2 3	No Kisqali	
Day 4	Kisqali Tablets: Al	1 2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 5	Kisqali Tablets: Al	1 2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 6	Kisqali Tablets: Al	1 2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
Day 7	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets:	1	2 3	No Kisqali	

Remember to take your aromatase inhibitor every day as directed by your doctor or nurse, even on days you do not take Kisqali unless you have been advised to stop both treatments.

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Questions abou	ut side effects	
Questions abou	ut tests	
Other question		
Other question	<u> </u>	

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Eating well, drinking plenty of fluids, exercising regularly and sleeping as much as you need can maintain your immune system and your strength



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	Start	t date:	Start	dat	e:	Start	dat	te:	Start date:	
Day 1	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
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Questions abo	ut dosing	
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Questions abo	ut side effects	
Questions abo	ut tests	
Other question	iS	

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Try to find something special in each day.

Stay busy and engaged with the healthy part of your life

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	We	ek 1	Wee	ek i	2	Wee	k:	3	Week 4	
	Start	t date:	Start	dat	:e:	Start (dat	te:	Start date:	
Day 1	Kisqali Tablets: Al	1 2 3	Kisqali Tablets:	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
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Questions abo	ut decina	
	ut dosing	
Questions abo	ut side effects	
Questions abo	ut tests	
Other question	ns	

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Your emotional health can be as important as your physical health, talk to your doctor or nurse if you feel that you need support



	Week 1			Wee	ek i	2	Week 3		Week 4		
	Start date:		Start date:		Start date:			Start date:			
Day 1	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets: Al	1	2 3	No Kisqali Al	
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Remember to take your aromatase inhibitor every day as directed by your doctor or nurse, even on days you do not take Kisqali unless you have been advised to stop both treatments.

Questions abo	out dosing	
	——————————————————————————————————————	
Questions abo	out side effects	
Questions abo	out tests	
Other questio	ns	

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Only you can decide when to share information with others.

Some people find chatrooms or meeting others with similar experiences useful. Your doctor or nurse may be able to direct you to your local support groups



	We	ek	1	Wee	ek i	2	Wee	ek :	3	Week 4	
	Start	da	te:	Start	dat	e:	Start	dat	te:	Start date:	
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Remember to take your aromatase inhibitor every day as directed by your doctor or nurse, even on days you do not take Kisqali unless you have been advised to stop both treatments.

do	nile on treatment, you may have questions. Write them wn here so that you can remember them for the next time u speak with your doctor or nurse.
Qu	estions about dosing
Qu	estions about side effects
Qu	estions about tests
Oth	ner questions

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It is important that you are confident in taking your treatment. Your doctor or nurse will welcome any question however small. As soon as you think you may have a side effect or an adverse reaction you must tell them



	Week 1		Week 2		Week 3			Week 4		
	Start date:		Start date:			Start date:			Start date:	
Day 1	Kisqali Tablets:	1 2 3	Kisqali Tablets: Al	1	2 3	Kisqali Tablets:	1	2 3	No Kisqali Al	
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Questions about si	de effects	
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Other questions		

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It is important to listen to your body, if you feel tired don't resist it, it is important to rest



Glossary

Aromatase inhibitor

A treatment that decreases the amount of oestrogen made by the body, which helps slow the growth of hormone **receptor**-positive cancer.

Cycle

A course of treatment that is repeated on a regular schedule.

Dose

The amount of medicine taken at one time.

Electrocardiogram (ECG)

A test that traces the electrical activity of the heart on a line graph. One heart abnormality that an ECG can test for is QT interval prolongation.

Electrolytes

Minerals in blood that carry an electric charge and affect a variety of body functions.

Fatigue

A feeling of extreme tiredness for an extended period of time.

Oestrogen

A hormone that all women normally have in their bodies that can sometimes make cancer cells grow.

Hormone

A chemical in the body that controls the activity of cells or organs.

Hormone receptor-positive (HR+)

Having cancer cells with hormone receptors.

Hormone (endocrine) therapy

Treatment that lowers the level of hormones in the body or blocks their action.

Human epidermal growth factor receptor 2-negative (HER2-)

Testing negative for a certain protein (HER2) found on the surface of cancer cells. HER2 can send signals for the cancer to grow.

Locally advanced or metastatic breast cancer

Cancer that has spread from the original tumour to other parts of the body. Sometimes, you may also hear this called advanced breast cancer or secondary breast cancer.

Menopause

The end of menstruation; the time of life when a woman stops having periods. This may have been artificially induced or have taken place naturally.

Neutropenia

When the body has an abnormally low concentration of **neutrophils**, leading to an increased risk of infection.

Neutrophil

A type of white blood cell that helps the body fight infection.

Protein

A large molecule made up of a chain of small chemical compounds, called amino acids. Proteins make up the structure of all cells and control how they work.

QT interval prolongation

When your heart takes longer than normal to refill with blood after it has contracted.

Receptor

A protein inside or on the surface of a cell to which substances can attach.

Side effect

An unwanted symptom caused by a medical treatment.

White blood cell

A type of blood cell that helps the body fight infection.



Finding the support you need

Below are some breast cancer charities that may be able to help you with understanding and managing your condition.

Find local support:



Breast Cancer Care https://www.breastcancercare.org.uk



Breast Cancer Now http://breastcancernow.org



Reporting of side effects

If you think you may be getting any side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack. Kisqali is subject to additional monitoring, this will allow quick identification of new safety information. You can help by reporting any side effects you may get. Please see www. mhra.gov.uk/yellowcard for instructions on how to report side effects.

You may wish to record some useful numbers here: Routine contact number Your doctor/nurse specialist:

In an emergency Emergency/acute oncology: