

TREATMENT AND SIDE EFFECTS

Ribociclib (Kisqali)

About this booklet

If you've been offered ribociclib as part of your breast cancer treatment, it's natural to have questions and concerns about how it may affect you.

This booklet explains what ribociclib is, how it's given and the side effects you may have.

What is ribociclib?

Ribociclib is a targeted therapy drug.

Targeted therapy is the name given to a group of drugs that block the growth and spread of cancer. They target and interfere with processes in the cells that help cancer grow.

Ribociclib belongs to a group of drugs called CDK 4/6 (cyclin dependent kinase) inhibitors. These drugs block the action of kinase, which is a protein that helps cells to grow and divide. This stops the growth and spread of cancer.

Ribociclib is the drug's non-branded name. You may hear it called by its brand name Kisqali.

Who might be offered ribociclib?

Ribociclib is used to treat breast cancer that's oestrogen receptor positive (ER-positive) and HER2-negative.

You may be offered ribociclib if you have:

- Primary breast cancer that your treatment team think has a higher risk of coming back (recurrence). If you have ribociclib after surgery, it's called adjuvant treatment
- Locally advanced breast cancer – breast cancer that has spread to the chest wall or skin of the breast, or the lymph nodes around the chest, neck and under the breastbone, but has not spread to other areas of the body. It cannot be removed with surgery
- Metastatic (secondary) breast cancer – breast cancer that has spread to another part of the body, such as the bones, lungs, liver or brain

How ribociclib is taken

For primary breast cancer, the usual dose of ribociclib is 400mg, taken as two 200mg tablets once a day.

For locally advanced or metastatic breast cancer, the usual dose is 600mg, taken as three 200mg tablets once a day.

You'll take ribociclib every day for 21 days, followed by a 7-day break. This is called a cycle. The cycle is then repeated.

You must take your tablets:

- About the same time each day
- Whole with water (do not crush, chew or dissolve them)

You can take them with or without food.

Ribociclib and hormone therapy

Ribociclib is always given alongside a hormone therapy drug to treat breast cancer. Hormone therapies block or stop the effect of oestrogen on breast cancer cells. Different hormone therapy drugs do this in different ways.

The hormone therapy drug you take will depend on whether you've been prescribed ribociclib for primary breast cancer or for locally advanced or metastatic breast cancer.

Ribociclib for primary breast cancer

If you're prescribed ribociclib for primary breast cancer, you will have it with an aromatase inhibitor (anastrozole, exemestane or letrozole).

You can find out more about these drugs in our individual drug booklets.

If you have not been through the menopause

If you have not been through the menopause (when your periods stop), you may also have treatment to stop your ovaries producing oestrogen, either temporarily or permanently. This is called ovarian suppression. Your treatment team will talk to you about this. And there's more information on ovarian suppression on our website.

If you're a man

Men who are prescribed ribociclib for primary breast cancer will usually have it with an aromatase inhibitor and an injection to suppress testosterone production.

Ribociclib for locally advanced or metastatic breast cancer

If you are prescribed ribociclib for locally advanced or metastatic breast cancer, you may have it with:

- An aromatase inhibitor (if you have not already had hormone therapy for locally advanced or metastatic breast cancer)
- Fulvestrant (if you have had an aromatase inhibitor for locally advanced or metastatic breast cancer)

If you have not had hormone therapy for locally advanced or metastatic breast cancer but you did have hormone therapy for primary breast cancer, you may be offered either of these drugs alongside ribociclib. The drug that's recommended will depend on your circumstances.

Ribociclib is offered in the same way to both men and women with locally advanced or secondary breast cancer.

You may be prescribed ribociclib if you have not been through the menopause (are premenopausal). If this is the case, you may have ribociclib together with ovarian suppression treatment. Your treatment team will talk to you about this.

Taking ribociclib with an aromatase inhibitor

You take an aromatase inhibitor drug once a day throughout the cycle.

Taking ribociclib with fulvestrant

Fulvestrant is given in 2 injections, 1 in each buttock. These are known as intramuscular injections. They are usually given every 2 weeks for the first 3 doses, then every 4 weeks for as long as you are having ribociclib.

What if I miss a dose of ribociclib?

If you miss a dose of ribociclib or you're sick (vomit) soon after taking it, do not take an extra dose to make up for the one you missed.

Take the next dose at the usual time and speak to someone in your treatment team.

How long will I take ribociclib for?

If you have primary breast cancer, you'll usually take ribociclib for 3 years alongside hormone therapy. After this you'll stop taking ribociclib, but you'll continue to have hormone therapy for a total of 5 or 10 years.

If you have metastatic breast cancer, you'll have ribociclib alongside hormone therapy for as long as your treatment team feels you're benefiting from the treatment and any side effects are manageable.

Side effects of ribociclib

Like any treatment, ribociclib can cause side effects. Everyone reacts differently to drugs and some people have more side effects than others. These side effects can usually be managed and those described here will not affect everyone.

As ribociclib is given with hormone therapy, it's sometimes difficult to know which side effects are being caused by which treatment.

If you're worried about any side effects, regardless of whether they're listed here, talk to your treatment team.

Common side effects of ribociclib

Effects on the blood

Ribociclib can temporarily affect the number of blood cells in the body. Blood is made up of red cells, white cells and platelets.

You'll have regular blood tests. If these show the number of blood cells is too low, your next cycle of treatment may be delayed or the dose reduced.

Your treatment team may change the dose of a drug to suit you and help manage its side effects. This may help you stay on the treatment for longer.

Anaemia

Having too few red blood cells is called anaemia. If you feel breathless, dizzy or particularly tired, let your treatment team know.

Risk of infection



Not having enough white blood cells can increase your risk of getting an infection.

Your treatment team may give you advice on reporting signs of an infection. But generally you should contact your hospital immediately if you have any of the following:

- A high temperature (over 37.5°C) or low temperature (under 36°C)
- Suddenly feeling unwell, even with a normal temperature
- Symptoms of an infection, such as a sore throat, cough, needing to pee often or feeling cold or shivery, even if you do not have a high temperature

Before starting treatment, you should be given a 24-hour contact number or told who to contact if you feel unwell at any time during your treatment, including overnight or at the weekends. You may need treatment if you get an infection.

Bruising and bleeding

Ribociclib can reduce the number of platelets. Platelets help the blood to clot.

If your platelets are low, you may:

- Bruise more easily
- Have nosebleeds
- Notice that your gums bleed when you brush your teeth
- Take longer to stop bleeding if you cut yourself

Tell your treatment team if you have any of these symptoms.

Extreme tiredness (cancer-related fatigue)

Fatigue is extreme tiredness that does not go away with rest or sleep.

Fatigue is a common side effect of ribociclib and may last for weeks or months after your treatment has finished.

Fatigue may affect how you cope with your cancer and its treatment. It can also make everyday activities harder and affect your quality of life.

If you think you have fatigue, tell your treatment team or GP. They can assess you and offer advice on how to manage your energy levels.

You can find more information on our website or by calling our helpline on **0808 800 6000**. Macmillan Cancer Support also produces information on coping with fatigue.

Sore mouth

Looking after your mouth, including your teeth and gums, is very important during treatment.

You may be given mouthwash to try to reduce soreness and prevent mouth ulcers developing. It's a good idea to use a small, soft toothbrush during this time.

See your dentist for a check-up before treatment begins. Avoid dental work during these treatments if possible.

If you do need to have dental work during treatment, talk with your treatment team about the best time to have this.

If you're having difficulty registering with a dentist, let your treatment team know.

Nausea and vomiting

You may feel sick (nausea) or be sick (vomit). Your treatment team can prescribe anti-sickness drugs to help with this if needed. Contact your treatment team if you are sick 3 or more times in 24 hours or are finding it difficult to eat and drink.

Loss of appetite

You may not feel like eating, especially if you're feeling sick. It might help to eat small meals regularly and drink plenty of liquids.

Tummy (abdominal) pain

You may have tummy pain or discomfort. Let your treatment team know so they can prescribe medication to help.

Diarrhoea and constipation

Tell your treatment team or GP if you have diarrhoea or constipation as they can prescribe drugs to help.

Contact your treatment team if you have diarrhoea 3 or more times in 24 hours, compared to what's usual for you.

Indigestion and heartburn

You may have indigestion or heartburn, which is a burning feeling in the lower chest. Let your treatment team know if you have any of these side effects. They can prescribe medications to help.

Skin changes

You might get a rash anywhere on your body.

You may also have dry skin. You may notice your skin is scaly, rough, tight or itchy.

Your treatment team may suggest drugs such as antihistamines to reduce any itching.

It may also help to:

- Use a moisturiser regularly and avoid perfumed products
- Use high factor sunscreen when out in the sun
- Protect your hands when doing household or outdoor chores
- Rinse and dry your hands carefully, particularly after contact with cleaning products
- Pat your skin dry with a soft towel, rather than rubbing vigorously
- Take care when shaving
- Wear clothing made of natural fibres (such as cotton) where possible and wash clothes in mild detergent

Hair thinning and hair loss

Taking ribociclib and hormone therapy can cause hair thinning or hair loss.

For more information about hair thinning or hair loss, see our **Breast cancer and hair loss** booklet.

Other common side effects

Other common side effects include:

- Back pain
- Headaches
- Dizziness

Your treatment team can advise you on how to manage these.

Less common side effects of ribociclib

Damage to the lungs (interstitial lung disease)

Ribociclib can cause interstitial lung disease (ILD). ILD can cause inflammation in your lungs, which can lead to scarring.

If ribociclib has caused inflammation to your lungs, you may need to stop treatment temporarily to prevent further damage. You may have steroids to treat the inflammation.

Contact your treatment team straight away if you have:

- Shortness of breath
- A cough, with or without a high temperature
- Any new or worsening breathing problems, such as chest tightness or wheezing

These symptoms could have a number of causes including side effects of treatment or a lung infection. It's important to let your treatment team know so that they can find out the cause. You may need a chest x-ray or CT scan to check what's causing your symptoms.

Heart rhythm changes

Ribociclib can cause a change in the way your heart beats.

Both before and during your treatment, you will have a test called an ECG (electrocardiogram), which takes an electrical recording of your heart.

Sometimes treatment may need to be delayed or the dose reduced if tests show any problems with your heart.

If you notice a change in your heartbeat or you feel dizzy or faint, contact your treatment team straight away.

Liver changes

Ribociclib can affect how the liver works.

You'll have blood tests to check how your liver is working while you're having treatment.

Treatment may need to be delayed or the dose reduced if the blood tests show any problems with your liver.

If you have any of the following symptoms, contact your treatment team straight away:

- Yellowing of your skin or the whites of your eyes (jaundice)
- Pain on your right side under the ribs
- Bleeding or bruising more easily than normal
- Feeling more tired
- Your pee being dark brown
- Itching

Eye problems

Ribociclib may cause changes to your eyes. For example, your eyes may become dry or produce more tears.

Contact your treatment team as soon as possible if you have any of these symptoms.

Change in taste

Your sense of taste may change and some food may taste different, for example more salty, bitter or metallic.

It can help to try different types of food to see what tastes best to you.

Rare side effects of ribociclib

Severe skin reaction

In locally advanced and metastatic breast cancer, ribociclib can cause a rare but potentially life-threatening skin condition called toxic epidermal necrolysis.

Symptoms include:

- Widespread rash
- Red skin
- Inflammation or blistering of the lips, eyes or mouth
- Skin peeling
- High fever
- Flu-like symptoms

Contact your treatment team straight away if you develop any of the symptoms above.

Blood clots



People with breast cancer have a higher risk of blood clots. Having ribociclib also increases the risk of blood clots such as a DVT (deep vein thrombosis).

If you have a DVT, there's a risk part of the blood clot could break away and travel to the lung. This is known as a pulmonary embolism (PE).

Blood clots can be life-threatening and should be treated quickly.

Contact your treatment team or go to your local A&E department straight away if you have any of the following symptoms:

- Pain in your arm or leg
- Redness/discolouration of the skin of the arm or leg
- Heat and swelling of the arm or leg
- Swelling, redness or tenderness where a central line is inserted to give chemotherapy, for example in the arm, chest area or up into the neck
- Shortness of breath that comes on suddenly
- Pain or tightness in the chest
- Unexplained cough or coughing up blood

Some symptoms, such as redness and discolouration, may look different on different skin tones.

Other important information

Medicines and food to avoid when taking ribociclib

When taking ribociclib:

- Do not take supplements containing St John's Wort
- Do not eat grapefruit or drink grapefruit juice

Always ask your treatment team before taking any herbal medicines or supplements.

Ribociclib contains an ingredient called soya lecithin. If you are allergic to peanuts or soya, you should not take ribociclib. Your treatment team will discuss this with you.

Some drugs should not be taken with ribociclib. These include some commonly prescribed antibiotics, antifungal, antiviral and anti-epileptic drugs.

Tell your treatment team about any prescribed or over-the-counter medicines you're taking, especially medicine that contains ketoconazole. This might include antifungal creams, gels or shampoos used to treat skin infections such as athlete's foot.

If a healthcare professional, such as your GP or dentist, prescribes you a new drug, tell them you're taking ribociclib.

INFO

Allergic reaction

Very occasionally, you can have an allergic reaction to ribociclib. Reactions can vary from mild to severe, although severe reactions are uncommon.

If you have a less severe reaction, you may need to take medication before future treatments to reduce the risk of further reactions.

Call the 24-hour contact number you were given immediately if you notice any of the following symptoms:

- Breathlessness, wheezing, a bad cough or sudden difficulty breathing
- Tight chest or chest pain
- Swelling in your lips, tongue or throat
- Itchy red or discoloured bumps on your skin (these may be harder to see on black or brown skin)

Sex, contraception and pregnancy

You can still have sex during treatment. It's thought some drugs used to treat breast cancer cannot pass into vaginal fluids or semen, but this cannot be completely ruled out.

Most treatment teams will advise using barrier methods of contraception, such as condoms or female condoms, during treatment and for at least 3 weeks after your last dose.

You're advised not to become pregnant while having treatment because ribociclib can harm a developing baby. If you have not been through the menopause, talk to your team about the most suitable method of contraception for you. It's still possible to become pregnant even if your periods are irregular or have stopped naturally or because of treatment for breast cancer.

Fertility

If you're a woman

It's not known if ribociclib affects fertility in women.

Conversations about fertility can be hard. It's important to discuss any fertility concerns with your treatment team before you begin your treatment. They will be able to talk to you about fertility preservation options.

If you're a man

Ribociclib may affect fertility in men. You may want to talk to your treatment team about sperm preservation before starting treatment.

Ribociclib and breastfeeding

You'll be advised not to breastfeed during treatment and for at least 3 weeks after your last dose. This is because there's a chance your baby may absorb the drug through your breast milk, which may be harmful for them.

Vaccinations and travel

Travel vaccinations

If you're planning a holiday or need to travel overseas, check with your treatment team first.

You should not have any live vaccines while you're having chemotherapy or targeted therapies.

Live vaccines include:

- Mumps
- Measles
- Rubella (German measles)
- Polio
- BCG (tuberculosis)
- Yellow fever

Live vaccines contain a small amount of live virus or bacteria. If you have a weakened immune system, which you may do during chemotherapy, they could be harmful.

It's safe to have these vaccinations 6 months after your treatment finishes. Talk to your GP or treatment team before having any vaccinations.

If anyone you have close contact with needs to have a live vaccine, speak to your treatment team or GP. They can advise what precautions you may need to take depending on the vaccination.

COVID-19 vaccination

If you're having chemotherapy or targeted therapies, your treatment team will advise the best time to have a COVID-19 vaccination.

Flu vaccination

Anyone at risk of a weakened immune system, and therefore more prone to infection, should have the flu vaccine. This includes people due to have, or already having, chemotherapy.

The flu vaccine is not a live vaccine so does not contain any active viruses.

Talk to your chemotherapy team or breast care nurse about the best time to have your flu jab.

Nasal flu vaccine for children

The nasal flu vaccine offered to children is a live vaccine. Let your treatment team know if someone you live with needs the nasal flu vaccine.

Further support

Being diagnosed with breast cancer can make you feel lonely and isolated. But there's support available. And you might find it helpful to talk to someone who knows what it's like.

Helpline

You can call our helpline on **0808 800 6000**, 9am to 4pm Monday to Friday and 9am to 1pm on Saturdays, to speak to one of our specialist nurses if you've got any questions or worries.

Forum

Join our online forum to speak to others who are having similar treatment to you. Visit **forum.breastcancer.org** to sign up.

Someone Like Me

If you've been diagnosed with primary breast cancer, our Someone Like Me service will match you with a trained volunteer who's had a similar experience to you. They'll be a phone call or email away to answer your questions, offer support or simply listen. Because there's nothing like finding someone who really understands.

Visit **breastcancer.org/support-for-you** to find out more.

Living with Secondary Breast Cancer groups

Our Living with Secondary Breast Cancer groups let you share experiences with other people who are also dealing with the uncertainty and challenges of metastatic breast cancer.

Visit **breastcancer.org/support-for-you** to find out more.



We're the UK's leading breast cancer charity. And we're combining the power of science and support to change breast cancer.

Life-saving science

Uncovering how breast cancer develops and spreads. New and better treatments that can find and destroy cancer cells. And one day, cures that can stop it in its tracks entirely.

Life-changing support

Expert information on everything from signs and symptoms to chemotherapy. Help so you can live well. Meeting people who are going through the same thing – people who just get it.

Change-making campaigns

Making sure everyone knows the importance of checking their breasts and chests, and the signs to look out for. Pushing for better diagnosis and care. Making sure everyone can get the drugs they need.

We don't get any government or NHS funding for our information or support. We rely on our supporters to make change happen.

So if you've found this information helpful and you'd like to support us, go to: **breastcancernow.org/give**

About this information

Ribociclib (Kisqali) was written by Breast Cancer Now's clinical specialists, and reviewed by healthcare professionals and people affected by breast cancer.



For a full list of the sources we used to research it:
Email **health-info@breastcancer.org**



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