

Ribociclib (Kisqali)

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1. What is ribociclib?

Ribociclib is a targeted or biological therapy drug.

When used to treat breast cancer, ribociclib is taken alongside hormone (endocrine) therapy.

Ribociclib is the drug's non-branded name. Its brand name is Kisqali.

It belongs to a group of drugs called CDK (cyclin dependent kinase) inhibitors. This group of drugs block the action of kinase, a protein that helps cells to grow and divide. By doing so, they stop the growth and spread of cancer.

2. Who might be offered ribociclib?

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

You may be offered ribociclib if your breast cancer has:

- Spread to the tissues and lymph nodes around the chest, neck and under the breastbone (locally advanced breast cancer)
- Spread to another part of the body such as the bones, lungs, liver or brain (secondary breast cancer)

Ribociclib is not currently given for early (primary) breast cancer, though clinical trials are looking at whether this may be useful.

3. Taking ribociclib

When taking ribociclib you must:

- Take the tablets whole with water (do not crush, chew or dissolve)
- Take the tablets at about the same time each day, preferably in the morning

The usual dose of ribociclib is 600mg, taken as three 200mg tablets.

It can be taken with or without food.

Ribociclib and hormone therapy

In the UK ribociclib is always given alongside a hormone therapy drug.

You may have ribociclib with:

- An aromatase inhibitor (anastrozole, exemestane or letrozole) if you have not already had hormone therapy for locally advanced or secondary breast cancer
- Fulvestrant if you have had hormone therapy for locally advanced or secondary breast cancer

Some people who had hormone therapy for primary breast cancer, and who now have locally advanced or secondary breast cancer, may be offered ribociclib with an aromatase inhibitor or fulvestrant. This will depend on their circumstances.

Taking ribociclib with an aromatase inhibitor

You take three ribociclib tablets a day for 21 days, followed by a seven-day break. This is known as a cycle.

The cycle is then repeated.

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

Taking ribociclib with fulvestrant

You take three ribociclib tablets a day for 21 days, followed by a seven-day break. This is known as a cycle.

The cycle is then repeated.

Fulvestrant is given in two injections, one into the muscle (intramuscular injections) of each buttock. They are usually given every 14 days for the first three doses, then every 28 days for as long as you are taking ribociclib.

If you have not been through the menopause

Aromatase inhibitors and fulvestrant are suitable for women who have been through the menopause (when your periods stop).

If you have not been through the menopause, you will also have treatment to stop the ovaries producing oestrogen, either temporarily or permanently. This is known as ovarian suppression.

What happens if I miss a dose?

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

Keep to your usual amount and speak to someone in your treatment team.

How long will I take ribociclib for?

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.

Medicines and food to avoid when taking ribociclib

When taking ribociclib:

- Do not take anything that contains St John's Wort
- Do not eat grapefruit or drink grapefruit juice

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

Tell your specialist about any prescribed or over-the-counter medicines you're taking.

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

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

Ribociclib contains soya lecithin. You should not take ribociclib if you are allergic to peanuts or soya.

4. Side effects of ribociclib

Like any drug, ribociclib can cause side effects. Everyone reacts differently to drugs and some people have more side effects than others.

You'll have regular hospital appointments with your treatment team to check whether you're experiencing side effects.

It can be helpful to keep a diary of how you feel while taking ribociclib to monitor any side effects.

Side effects can usually be controlled and those described here will not affect everyone.

Because it's given alongside hormone therapy, you may have side effects from that drug as well.

If you're concerned about any side effects, regardless of whether they're listed here, tell your treatment team.

Common side effects

Effects on the blood

Ribociclib can temporarily affect the number of healthy blood cells in the body.

You'll have regular blood tests both before and throughout your treatment to check your blood count.

It's recommended that blood tests are done before you start treatment, every two weeks for the first two cycles of treatment, then every four weeks before each of the next four cycles. After this your treatment team will decide how often you need a blood test.

Risk of infection

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

Infections such as gastroenteritis, urinary tract infections and chest infections are common while taking ribociclib.

When the white blood cells fall below a certain level, it's known as neutropenia. Having a high temperature with neutropenia (known as febrile neutropenia) is less common and occurs much less frequently than with chemotherapy.

Contact your hospital immediately if you:

- **Have a high temperature (over 37.5°C) or low temperature (under 36°C), or whatever your treatment team has advised**

- **Suddenly feel unwell, even with a normal temperature**
- **Have any symptoms of an infection, for example a sore throat, a cough, a need to pass urine frequently or feeling cold or shivery**

Before you start ribociclib your treatment team should give you a 24-hour contact number or tell you where to get emergency care.

Low white cell blood counts are very common when taking ribociclib. The number of white blood cells usually returns to normal before your next cycle of treatment.

If you develop low white blood cell counts during treatment with ribociclib, your doctor may decrease the dose, delay your next cycle of treatment or stop your treatment.

Anaemia

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

Bruising and bleeding

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

You may bruise more easily, have nosebleeds or your gums may bleed when you brush your teeth. Tell your treatment team if you have any of these symptoms.

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
- Passing dark brown urine

Cancer related fatigue (extreme tiredness)

Cancer-related fatigue is extreme tiredness that doesn't go away with rest or sleep.

It's a very common side effect of secondary breast cancer and its treatment and may affect you physically and emotionally.

It has many causes, from psychological factors such as the stress of coping with the diagnosis, to physical ones such as the side effects of treatment or growth and spread of the cancer.

Fatigue may have a significant effect on your ability to cope with your cancer and its treatment. It can also affect your everyday activities and quality of life.

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

Find out more about [managing fatigue](#).

Shortness of breath and cough

These are usually mild.

Let your treatment team know if you experience symptoms such as a worsening cough, breathlessness or wheezing, or if any existing breathing problems get worse.

Sore mouth

Your mouth may become sore, dry or painful and you may get ulcers.

You may be given mouthwash to reduce soreness of the mouth and gums and to try to stop mouth ulcers developing.

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

It's advisable to see your dentist for a dental check-up before your treatment begins. Check with your treatment team before having any dental work done.

Nausea and vomiting

You may feel sick (nausea) or be sick (vomit). Although not usually needed, anti-sickness drugs can be prescribed to help with this.

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 abdominal pain or discomfort. Let your treatment team know so they can prescribe medication to help.

Diarrhoea and constipation

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

Contact your treatment team if you have four or more episodes of diarrhoea within a 24-hour period. Drink plenty of fluids to avoid getting dehydrated.

Rash

This can be uncomfortable but regularly using a moisturiser and, when out in the sun, a high factor sunscreen may help.

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

Hair thinning and hair loss

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

Find out more about [hair loss](#).

Other common side effects

Other common side effects include:

- Shortness of breath
- Back pain
- Headaches
- Dizziness

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

Less common side effects

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.

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. They can arrange for you to see an optician if necessary.

Dry skin

You may have dry skin. This can include mild scaling, roughness, feelings of tightness or itching.

It may help to:

- Use a moisturiser regularly and avoid perfumed products
- 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 cotton clothes where possible next to the skin and wash clothes in mild detergent

Change in taste and indigestion

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

It can help to try different types of food to find the ones you prefer to eat.

You may also 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.

Inflammation of the lungs

Ribociclib can cause severe inflammation of the lungs.

Contact your treatment team straight away if you have any new or worsening symptoms involving your lungs including:

- Difficulty or discomfort with breathing
- Shortness of breath at rest or during mild activity
- Dry cough
- Chest pain

Rare side effects of ribociclib

Severe skin reaction

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.

5. Other important information

Allergic reaction

Very occasionally allergic reactions to ribociclib can occur. Reactions may vary from mild to severe, although severe reactions are uncommon.

If you have any swelling, wheezing, chest pain or difficulty breathing after taking ribociclib, contact your local A&E department, GP or treatment team immediately.

Blood clots

People with breast cancer have a higher risk of blood clots such as a deep vein thrombosis (DVT). Their risk is higher because of the cancer itself and some treatments for breast cancer. When cancer has spread to other parts of the body like in secondary breast cancer, this also increases the risk.

People with a DVT are at risk of developing a pulmonary embolism (PE). This is when part of the blood clot breaks away and travels to the lung.

Blood clots can be harmful but are treatable so it's important to report symptoms as soon as possible.

If you experience any of the following symptoms contact your local A&E department, GP or treatment team straight away:

- Pain, redness/discolouration, heat and swelling of the calf or thigh
- 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
- Tightness in the chest
- Unexplained cough or coughing up blood

Find out more about [blood clots](#).

Sex, contraception and pregnancy

Taking ribociclib while pregnant may be harmful to a developing baby.

Barrier contraception should be used during treatment and for at least three weeks after stopping treatment.

Some women can still become pregnant even if their periods are irregular or have stopped.

While women's fertility may not be affected, ribociclib can decrease fertility in men. Men taking ribociclib may want to talk to their treatment team about sperm preservation before starting treatment.

Ribociclib and breastfeeding

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

Vaccinations

Always check with your treatment team before having any vaccinations while taking ribociclib.

You shouldn't have any live vaccines, which include measles, rubella (German measles), polio, BCG (tuberculosis), shingles and yellow fever.

Live vaccines contain a small amount of live virus or bacteria. These could be harmful and cause infections.

If you're planning a trip and need vaccinations, discuss this with your treatment team.

If someone you live 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.

Flu vaccination

Anyone at risk of a weakened immune system, and therefore more prone to infection, should have the flu vaccine. This includes people having, or due to have, treatment for breast cancer. The flu vaccine is not a live vaccine so doesn't contain any active viruses. Talk to your treatment team about the best time to have your flu jab.

Coronavirus (Covid-19) vaccination

People having ribociclib are advised to speak to their treatment team before having the coronavirus (Covid-19) vaccination.

Find out more about the [coronavirus vaccine](#).

6. Further support

Being diagnosed with breast cancer can make you feel lonely and isolated.

Many people find it helps to talk to someone who has been through the same experience as them.

[Living with Secondary Breast Cancer Online programme](#) and virtual meetings let you share experiences with other people dealing with the uncertainty and challenges of secondary breast cancer.

If you would like any further information and support about breast cancer or just want to talk things through, you can speak to one of our experts by calling our free [Helpline](#) on 0808 800 6000.

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Next planned review begins 2023