1. What is ribociclib?
Ribociclib is a targeted (biological) therapy. This group of drugs block the growth and spread of cancer. They target and interfere with processes in the cells that cause cancer to grow. Ribociclib is the generic (non-branded name). Its branded name is Kisqali. When used to treat breast cancer, ribociclib is taken alongside hormone (endocrine) therapy.

2. Who might be offered ribociclib?
Ribociclib may be offered to people who have **locally advanced** or **secondary breast cancer** that is both:

- **oestrogen receptor positive (ER+)** (where the hormone oestrogen ‘helps’ the breast cancer to grow)
- **HER2 negative** (breast cancer that has a normal level of the HER2 protein)

### If you haven’t had treatment for locally advanced or secondary breast cancer

You may be given ribociclib in combination with an **aromatase inhibitor**.

Women who have been through the menopause may be offered ribociclib in combination with **fulvestrant**.

### If you’ve had hormone therapy for secondary breast cancer

Some people may be offered ribociclib in combination with an aromatase inhibitor or fulvestrant.

If you haven’t been through the menopause (when your periods stop) you will also have treatment to stop the ovaries producing oestrogen, either temporarily or permanently. This is known as **ovarian suppression**.

### If your breast cancer has come back while taking hormone therapy for primary breast cancer

Some people may be offered ribociclib in combination with fulvestrant.

### Availability

Ribociclib is currently available on the NHS throughout the UK for people who haven’t already had any treatment for locally advanced or secondary breast cancer, in combination with an aromatase inhibitor.

It is also currently available in England through the Cancer Drugs Fund:

- for people who have had hormone therapy for locally advanced or secondary breast cancer, in combination with fulvestrant
- for some people whose breast cancer has not responded to treatment, or has come back, while taking hormone therapy for primary breast cancer, in combination with fulvestrant
You may be offered ribociclib as part of a clinical trial.

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

3. How does ribociclib work?

Certain proteins in the body cause cells to grow and divide. In ER positive (ER+), HER2 negative breast cancer, these proteins can become overactive and 'help' breast cancer cells to grow. Ribociclib works by blocking these proteins, helping to stop the cancer cells growing and dividing.

When combined with hormone therapies that block the effects of oestrogen on cancer cells, ribociclib helps to delay the growth of ER+, HER2 negative breast cancer.

4. How is ribociclib given?

Ribociclib is given as three 200mg tablets (600mg) that must be taken whole with water, at about the same time each day. It can be taken with or without food.

Ribociclib is always given alongside a hormone therapy.

If you’re taking ribociclib with an aromatase inhibitor

Ribociclib is taken over a four-week cycle. For the first 21 days three tablets are taken daily, followed by a seven-day break. An aromatase inhibitor drug is taken once a day continually throughout the 28 days. The cycle is then repeated.

If you’re taking ribociclib with fulvestrant

Ribociclib is taken over a four-week cycle. For the first 21 days three tablets are taken daily, followed by a seven-day break. The cycle is then repeated.

Fulvestrant is given in two injections, one in each buttock. These are known as intramuscular (IM) injections. It’s usually given every two weeks for the first three doses, then once a month for as long as you are taking ribociclib.
What happens if I miss a dose?

If you miss a dose of ribociclib, or 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 specialist team.

How long will I take ribociclib for?

You’ll have ribociclib alongside hormone therapy for as long as your specialist team feels you’re benefiting from the treatment and you are tolerating it.

5. Common 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. These side effects can usually be controlled and those described here will not affect everyone.

Because it’s given alongside hormone therapy, you may also experience side effects from that drug as well.

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

Effects on the blood

Ribociclib can temporarily affect the number of healthy blood cells in the body. Blood cells (white blood cells, red blood cells and platelets) are made by the bone marrow (the spongy material found in the hollow part of bones) to replace those which are naturally used up in the body. Ribociclib reduces the ability of the bone marrow to make these cells.

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, then every two weeks for the first two cycles of treatment, and before each of the next four cycles.

Risk of infection
When the white blood cells fall below a certain level, it’s known as neutropenia. Not having enough white blood cells can increase the risk of getting an infection. Urinary tract infections are the commonest infection while taking ribociclib.

The number of white blood cells usually returns to normal before your next cycle of treatment. Low white cell blood counts are very common when taking ribociclib. 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 specialist team has advised
- you suddenly feel unwell, even with a normal temperature
- you have any symptoms of an infection, for example a sore throat, a cough, a need to pass urine frequently or feeling cold and/or shivery

Before starting ribociclib you should be given a 24-hour contact number or told where to get emergency care by your specialist team. You may need antibiotics.

If you develop low white blood cell counts or problems with your liver or heart function 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 specialist 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 specialist team if you experience any of these symptoms.

**Fatigue (extreme tiredness)**

It's common to feel extremely tired during your treatment. There are different ways of coping with and managing fatigue. You can speak to your specialist team or contact Breast Cancer Now for more information and support.
**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.

**Sore mouth**

Your mouth may become sore or dry 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.

Good mouth hygiene is very important during treatment. It’s advisable to see your dentist for a dental check-up before your treatment begins. Check with your specialist team before having any dental work done.

**Nausea and vomiting**

You may experience nausea (feeling sick) and vomiting (being sick). Although not usually needed, anti-sickness drugs can be prescribed to help with this.

**Diarrhoea**

Tell your specialist or GP if you have diarrhoea as they can prescribe drugs to help. Contact your specialist 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 using a moisturiser and a high factor sunscreen may help. Your specialist team may suggest drugs such as antihistamines to reduce any itching.

**Hair thinning and hair loss**

Ribociclib can cause hair thinning or hair loss. For more information you can download our *Breast cancer and hair loss* booklet.

Other common side effects include headaches, backache and difficulty sleeping. Your specialist team will be able to advise you on how to manage these.
6. Less common side effects of ribociclib

Liver changes
Ribociclib can cause problems in the liver. You will have blood tests to check your liver function while you’re having treatment.

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

If you experience any of the following symptoms contact your specialist 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

Heart changes
Ribociclib can cause a change in the way your heart beats. Both before and during your treatment, you will have a cardiac (heart) function test called an electrocardiogram (ECG), 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 experience a change in your heart beat, or feel dizzy or faint, contact your specialist team straight away.

Blurred vision, dry eye and increased tears
Ribociclib may cause eyesight changes such as blurred vision, dry eyes and increased tear production.

It’s important to contact your specialist 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 experience dry skin including mild scaling, roughness, feeling of tightness or itching.
It may help to:

- use a moisturiser regularly and avoid perfumed products
- protect your hands when doing household/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**

Your taste can change and some food may taste different (for example more salty, bitter or metallic). It can be helpful to experiment with different types of food to find the ones you prefer to eat.

**7. Rare side effects of ribociclib**

**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 hospital immediately.

**8. Blood clots**

People with breast cancer have a higher risk of blood clots. Their risk is higher because of the cancer itself and some treatments for breast cancer. If the cancer has spread to other parts of the body (secondary breast cancer), this also increases the risk.

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 specialist team straight away:
• pain, redness/discolouration, heat and swelling of the calf, leg 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 (may cough up blood)

Find out more about blood clots »

9. Medicines and food to avoid when taking ribociclib

There are a number of drugs that should not be taken with ribociclib, so it’s important to tell your specialist about any prescribed or over-the-counter medicines you are taking, especially medicines used to treat heart rhythm problems or high blood pressure. If a healthcare professional (such as your GP or dentist) prescribes you a new drug, you should tell them you’re taking ribociclib.

Many people consider taking herbal medicines or supplements while having treatment for breast cancer. Ribociclib must not be taken with anything containing St John’s wort. You should ask for advice from your specialist before taking any herbal medicines or supplements.

Eating grapefruit or pomegranates, or drinking grapefruit or pomegranate juice should also be avoided while you are taking ribociclib.

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

10. Sex and contraception

Taking ribociclib while pregnant may be harmful to a developing baby. Some women can still become pregnant even if their periods are irregular or have stopped.

Women should continue using an effective barrier contraception during and for at least three weeks after stopping treatment.
Men taking ribociclib should use effective contraception during and for 14 weeks after stopping treatment.

While female fertility may not be affected, ribociclib can decrease fertility in men. Men taking ribociclib may want to talk to their specialist team about sperm preservation prior to treatment starting.

**Ribociclib and breastfeeding**

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

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**11. Vaccinations**

You shouldn’t have any live vaccines while you’re having ribociclib. Live vaccines 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 specialist team.

If someone you live with needs to have a live vaccine speak to your specialist 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. If you’re already having treatment, talk to your specialist team about the best time to have your flu jab.

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**12. 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. Breast Cancer Now’s Living with Secondary Breast Cancer service can provide an opportunity to meet those in a similar situation, and offers helpful support and information in a relaxed environment. You might also find it helpful to join one of our Live Chat sessions, or visit our confidential online Forum.

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.

Last reviewed: March 2018, revised August 2019
Next planned review begins 2020