

Package leaflet: Information for the patient

Kisqali® 200 mg film-coated tablets ribociclib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kisqali is and what it is used for
2. What you need to know before you take Kisqali
3. How to take Kisqali
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1. What Kisqali is and what it is used for

What Kisqali is

Kisqali contains the active substance ribociclib, which belongs to a group of medicines called cyclin-dependent kinase (CDK) 4 and 6 inhibitors.

What Kisqali is used for

Kisqali is used in patients with a type of breast cancer called hormone receptor-positive and human epidermal growth factor receptor (HER2)-negative breast cancer that is:

- localised to the breast or could have spread to the lymph nodes in the region of the breast, with no detectable spread to other parts of the body, has been surgically removed, and has certain characteristics that increase the risk of the cancer returning. It is used in combination with an aromatase inhibitor, which is used as hormonal anticancer therapy (early breast cancer). Women who have not reached menopause, and men, will also be treated with a medicine called a luteinising hormone-releasing hormone (LHRH) agonist that blocks the production of some hormones.
- either advanced or metastatic. This means the cancer has grown outside the breast and spread to the lymph nodes of the breast (locally advanced) or has spread to other parts of the body (metastatic). Kisqali is used in combination with an aromatase inhibitor or fulvestrant, which are used as hormonal anticancer therapies. Women who have not reached menopause will also be treated with a medicine called a luteinising hormone-releasing hormone (LHRH) agonist that blocks the production of some hormones.

How Kisqali works

Kisqali works by stopping the growth signals transmitted by CDK 4 and 6 proteins, and thereby stopping cancer cells from growing and spreading. In early breast cancer, it can prevent the cancer from coming back after surgery (treatment after surgery is called adjuvant therapy). In advanced or metastatic breast cancer, it can delay progression of the cancer.

If you have any questions about how Kisqali works or why this medicine has been prescribed for you, ask your doctor, pharmacist or nurse.

2. What you need to know before you take Kisqali

Follow all of your doctor's instructions carefully. They may differ from the general information in this leaflet.

Do not take Kisqali

- if you are allergic to ribociclib, peanut, soya or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Kisqali.

If any of the following apply to you before taking Kisqali, tell your doctor or pharmacist:

- If you have a fever, sore throat or mouth ulcers due to infections (signs of a low level of white blood cells).
- If you have any problems with your liver or have previously had any type of liver disease.
- If you have or have had heart disorders or heart rhythm disorders, such as an irregular heartbeat, including a condition called prolonged QT syndrome (QT interval prolongation) or low levels of potassium, magnesium, calcium or phosphorus in your blood.

If any of the following apply to you during your treatment with Kisqali, tell your doctor or pharmacist:

- If you have a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (may be signs of a severe skin reaction).
In case of a severe skin reaction, your doctor will ask you to immediately stop treatment with Kisqali.
- Trouble breathing, cough and shortness of breath (may be signs of lung or breathing problems).
If necessary, your doctor may interrupt or reduce your dose of Kisqali or decide to stop treatment with Kisqali permanently.

Monitoring during your treatment with Kisqali

You will have regular blood tests before and during treatment with Kisqali to check your liver function and the amount of blood cells (white blood cells, red blood cells and platelets) and electrolytes (blood salts including potassium, calcium, magnesium and phosphate) in your body. Your heart activity will also be monitored before and during treatment with Kisqali with a test called an electrocardiogram (ECG). If necessary, additional tests to evaluate your kidney function will be performed during treatment with Kisqali. If necessary, your doctor may reduce your dose of Kisqali or temporarily stop it to allow your liver, kidney, blood cells, electrolyte levels or heart activity to recover. Your doctor may also decide to stop treatment with Kisqali permanently.

Children and adolescents

Kisqali is not to be used in children and adolescents under 18 years of age.

Other medicines and Kisqali

Before you take Kisqali, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including prescription and non-prescription medicines, herbal medicines, or supplements, because these may influence the effect of Kisqali. Always tell your doctor if you are prescribed a new medicine after you have started treatment with Kisqali.

This includes in particular:

- Tamoxifen, another medicine for the treatment of breast cancer.
- Some medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole or posaconazole.
- Some medicines used to treat HIV/AIDS such as ritonavir, saquinavir, indinavir, lopinavir, nelfinavir, telaprevir and efavirenz.

- Some medicines used to treat seizures or fits (anti-epileptics) such as carbamazepine and phenytoin.
- St. John's Wort (also known as *Hypericum perforatum*) - a herbal product used to treat depression and other conditions.
- Some medicines used to treat heart rhythm problems or high blood pressure such as amiodarone, disopyramide, procainamide, quinidine, sotalol and verapamil.
- Antimalarials such as chloroquine.
- Antibiotics such as clarithromycin, telithromycin, moxifloxacin, rifampicin, ciprofloxacin, levofloxacin and azithromycin.
- Some medicines used for sedation or anaesthesia such as midazolam.
- Some medicines used as antipsychotics such as haloperidol.
- Medicines used to treat angina such as bepridil.
- Methadone, used to treat pain or addiction to opioids.
- Medicines like intravenous ondansetron, used to prevent nausea and vomiting caused by chemotherapy (treatment with cancer medicines).

Kisqali may increase or decrease your blood levels of some other medicines. This includes in particular:

- Medicines used to treat symptoms of benign prostatic hyperplasia such as alfuzosin.
- Tamoxifen, another medicine used for the treatment of breast cancer.
- Antiarrhythmics such as amiodarone or quinidine.
- Antipsychotics such as pimozide or quetiapine.
- Medicines used to improve blood fat levels such as simvastatin or lovastatin, pitavastatin, pravastatin or rosuvastatin.
- Medicines used to treat high blood sugar levels (e.g. diabetes) such as metformin.
- Medicines used to treat cardiac disorders such as digoxin.
- Medicines used to treat pulmonary arterial hypertension and erectile dysfunction such as sildenafil.
- Medicines used to treat low blood pressure or migraine such as ergotamine or dihydroergotamine.
- Some medicines used to treat epileptic fits or which are used for sedation or anaesthesia such as midazolam.
- Medicines used to treat sleep disorders such as triazolam.
- Analgesics such as alfentanil and fentanyl.
- Medicines used for the treatment of gastrointestinal disorders such as cisapride.
- Medicines used to prevent the rejection of an organ transplant such as tacrolimus, sirolimus and ciclosporin (also used to treat inflammation in rheumatoid arthritis and psoriasis).
- Everolimus, used for several types of cancer and tuberous sclerosis (also used to prevent the rejection of an organ transplant).

Ask your doctor or pharmacist if you are not sure if your medicine is one of the medicines listed above.

Kisqali with food and drink

Do not eat grapefruits or foods that contain grapefruit or drink juices that contain grapefruit during your treatment with Kisqali. It may change how Kisqali is processed in your body and may increase the amount of Kisqali in your bloodstream.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will discuss with you the potential risks of taking Kisqali during pregnancy.

Pregnancy and women of childbearing potential

Kisqali should not be used during pregnancy since it may harm your unborn baby. If you are a woman

of childbearing potential you should have a negative pregnancy test before starting treatment with Kisqali. You should use effective contraception (e.g. double-barrier contraception such as condom and diaphragm) while taking Kisqali and for at least 21 days after the last dose. Ask your doctor about options for effective contraception.

Breast-feeding

You should not breast-feed while taking Kisqali and for at least 21 days after the last dose.

Driving and using machines

Treatment with Kisqali may lead to tiredness, dizziness or spinning sensation. You should therefore be cautious when driving or using machines during your treatment with Kisqali.

Kisqali contains soya lecithin

If you are allergic to peanut or soya, do not use this medicine.

3. How to take Kisqali

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Your doctor, pharmacist or nurse will tell you exactly how many tablets to take and which days to take them on. Check with your doctor, pharmacist or nurse if you are not sure. Do not change the Kisqali dose or schedule without talking to your doctor.

Do not exceed the recommended dose prescribed by your doctor.

How much Kisqali to take

	Recommended starting dose of Kisqali	Number of tablets
Early breast cancer	400 mg once daily	2 tablets of 200 mg
Advanced or metastatic breast cancer	600 mg once daily	3 tablets of 200 mg
Note: A treatment cycle lasts 28 days. Take Kisqali once a day only on days 1 to 21 of a 28-day cycle. Do not take Kisqali on days 22 to 28 of the cycle.		

- The outer carton of the Kisqali pack includes a “calendar tool” which allows you to track your daily Kisqali dose by marking off a circle for every tablet you take over the 28-day cycle.
- Your doctor will tell you exactly how many tablets of Kisqali to take. In certain situations (e.g. in case of liver or kidney problems) your doctor may instruct you to take a lower dose of Kisqali.

It is very important to follow your doctor’s instructions. If you get certain side effects your doctor may ask you to take a lower dose, interrupt your treatment with Kisqali, or stop it permanently.

When to take Kisqali

Take Kisqali once daily at the same time each day, preferably in the morning. This will help you to remember to take your medicine and to notice any side effects that may occur so that you can promptly contact your doctor.

How to take Kisqali

Kisqali tablets should be swallowed whole (tablets should not be chewed, crushed or split before swallowing). Do not take a tablet that is broken, cracked or otherwise damaged.

Kisqali with food and drink

You should take Kisqali once daily every day at the same time, preferably in the morning. You may take it with or without food.

How long to take Kisqali

Take Kisqali once a day on days 1 to 21 of a 28-day cycle. Continue Kisqali treatment for as long as your doctor tells you to.

In early breast cancer, a maximum of 3-year treatment duration is recommended. In advanced or metastatic breast cancer, this is a long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Kisqali than you should

If you take too many tablets, or if someone else takes your medicine, contact a doctor or hospital for advice immediately. Show the Kisqali packet. Medical treatment may be necessary.

If you miss a dose of Kisqali

If you vomit after taking the dose or forget a dose, skip the missed dose that day. Take the next dose at your usual time the next day.

Do not take a double dose to make up for a missed dose. Instead, wait until it is time for your next scheduled dose and then take your usual dose.

If you stop taking Kisqali

If you think that your dose is too high or too low, contact your doctor. Do not stop taking Kisqali unless your doctor tells you to. Stopping your treatment with Kisqali may cause your cancer to get worse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Read this section carefully. Side effects that might be serious are presented first (“**Some side effects could be serious**”), followed by all other side effects (“**Other possible side effects**”) in descending order of frequency.

Early breast cancer

Some side effects could be serious.

Your doctor may ask you to take a lower dose, interrupt your treatment with Kisqali, or stop it permanently. Tell your doctor immediately if you get any of the following symptoms during treatment with Kisqali:

- Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhoea or stomach pain, or feeling very tired (signs or symptoms of infections). *Very common (may affect more than 1 in 10 people).*
- Fever, chills, weakness and frequent infections with symptoms such as sore throat or mouth ulcers. These may be signs of either a low level of white blood cells (*very common, may affect more than 1 in 10 people*) or a low level of lymphocytes, which are a specific type of white blood cell (*common, may affect up to 1 in 10 people*).
- Abnormal results of blood tests that give information about the health of the liver (abnormal liver function tests). *Very common (may affect more than 1 in 10 people).*
- Spontaneous bleeding or bruising (signs of a low level of blood platelets). *Common (may affect up to 1 in 10 people).*
- Reduced level of potassium in the blood, which could lead to disturbances in heart rhythm. *Common (may affect up to 1 in 10 people).*
- Chest pain or discomfort, changes in heart beat (fast or slow), palpitations, lightheadedness, fainting, dizziness, lips turning blue colour, shortness of breath, swelling (oedema) of your lower limbs or skin (these may be signs of heart problems). *Common (may affect up to 1 in 10 people).*

- Tiredness, itchy yellow skin or yellowing of the whites of your eyes, nausea or vomiting, loss of appetite, pain in the upper right side of the belly (abdomen), dark or brown urine, bleeding or bruising more easily than normal (these may be signs of a liver problem). *Common (may affect up to 1 in 10 people).*
- Inflammation of the lungs, which can cause dry cough, chest pain, fever, shortness of breath and breathing difficulty (these may be signs of interstitial lung disease/pneumonitis which, if severe, may be life threatening). *Common (may affect up to 1 in 10 people).*
- Sore throat or mouth ulcers with a single episode of fever of at least 38.3°C or fever above 38°C for more than one hour and/or with infection (febrile neutropenia). *Uncommon (may affect up to 1 in 100 people).*

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, tell your doctor, pharmacist or nurse.

Very common (may affect more than 1 in 10 people)

- Sore throat, runny nose, fever (signs of a respiratory tract infection)
- Painful and frequent urination (signs of a urinary tract infection)
- Nausea (feeling sick)
- Headache
- Fatigue (tiredness)
- Asthenia (weakness)
- Alopecia (hair loss or hair thinning)
- Diarrhoea
- Constipation
- Cough
- Abdominal (belly) pain
- Pyrexia (fever)

Common (may affect up to 1 in 10 people)

- Rash
- Dizziness or light headedness
- Tiredness, pale skin (potential sign of a low level of red blood cells, anaemia)
- Vomiting
- Pruritis (itching)
- Peripheral oedema (swollen hands, ankles or feet)
- Dyspnoea (shortness of breath, difficulty breathing)
- Stomatitis (mouth sores with gum inflammation)
- Oropharyngeal pain (sore throat)
- Reduced level of calcium in the blood, which may sometimes lead to cramps
- Reduced appetite
- Abnormal kidney blood test result (high level of creatinine in the blood)

Advanced or metastatic breast cancer

Some side effects could be serious.

Your doctor may ask you to take a lower dose, interrupt your treatment with Kisqali, or stop it permanently. Tell your doctor immediately if you get any of the following symptoms during treatment with Kisqali:

- Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhoea or stomach pain, or feeling very tired (signs or symptoms of infections). *Very common (may affect more than 1 in 10 people).*
- Fever, chills, weakness and frequent infections with symptoms such as sore throat or mouth ulcers (signs of a low level of leukocytes or lymphocytes, which are types of white blood cells). *Very common (may affect more than 1 in 10 people).*

- Abnormal results of blood tests that give information about the health of the liver (abnormal liver function tests). *Very common (may affect more than 1 in 10 people).*
- Spontaneous bleeding or bruising (signs of a low level of blood platelets). *Common (may affect up to 1 in 10 people).*
- Sore throat or mouth ulcers with a single episode of fever of at least 38.3°C or fever above 38°C for more than one hour and/or with infection (febrile neutropenia). *Common (may affect up to 1 in 10 people).*
- Tiredness, itchy yellow skin or yellowing of the whites of your eyes, nausea or vomiting, loss of appetite, pain in the upper right side of the belly (abdomen), dark or brown urine, bleeding or bruising more easily than normal (these may be signs of a liver problem). *Common (may affect up to 1 in 10 people).*
- Reduced level of potassium in the blood, which could lead to disturbances in heart rhythm. *Common (may affect up to 1 in 10 people).*
- Chest pain or discomfort, changes in heart beat (fast or slow), palpitations, lightheadedness, fainting, dizziness, lips turning blue colour, shortness of breath, swelling (oedema) of your lower limbs or skin (these may be signs of heart problems). *Common (may affect up to 1 in 10 people).*
- Inflammation of the lungs, which can cause dry cough, chest pain, fever, shortness of breath and breathing difficulty (these may be signs of interstitial lung disease/pneumonitis which, if severe, may be life threatening). *Common (may affect up to 1 in 10 people).*
- Serious infection with increased heart rate, shortness of breath or rapid breathing, fever and chills (these may be signs of sepsis which is an infection in the blood system which may be life threatening). *Uncommon (may affect up to 1 in 100 people).*
- Severe skin reaction that might include a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (toxic epidermal necrolysis [TEN]). *Frequency not known (frequency cannot be estimated from the available data).*

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, tell your doctor, pharmacist or nurse.

Very common (may affect more than 1 in 10 people)

- Tiredness, pale skin (potential sign of a low level of red blood cells, anaemia)
- Sore throat, runny nose, fever (signs of a respiratory tract infection)
- Painful and frequent urination (signs of a urinary tract infection)
- Reduced appetite
- Headache
- Dizziness or light headedness
- Dyspnoea (shortness of breath, difficulty breathing)
- Cough
- Nausea (feeling sick)
- Diarrhoea
- Vomiting
- Constipation
- Abdominal (belly) pain
- Stomatitis (mouth sores with gum inflammation)
- Dyspepsia (upset stomach, indigestion, heartburn)
- Alopecia (hair loss or hair thinning)
- Rash
- Pruritis (itching)
- Back pain
- Fatigue (tiredness)
- Peripheral oedema (swollen hands, ankles or feet)
- Pyrexia (fever)

- Asthenia (weakness)

Common (*may affect up to 1 in 10 people*)

- Abdominal pain, nausea, vomiting and diarrhoea (signs of gastroenteritis, which is an infection of the gastrointestinal tract)
- Reduced level of calcium in the blood, which may sometimes lead to cramps
- Reduced level of phosphate in the blood
- Vertigo (spinning sensation)
- Watering eyes
- Dry eyes
- Reduced level of potassium in the blood, which could lead to disturbance in heart rhythm
- Dysgeusia (strange taste in the mouth)
- Dry skin
- Erythema (skin reddening)
- Vitiligo (loss of skin colour in patches)
- Oropharyngeal pain (sore throat)
- Dry mouth
- Abnormal kidney blood test result (high level of creatinine in the blood)

Rare (*may affect up to 1 in 1 000 people*)

- A skin reaction that causes red spots or patches on the skin that may look like a target or “bullseye” with a dark red centre surrounded by paler red rings (erythema multiforme)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kisqali

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Pharmacy: Store in a refrigerator (2°C - 8°C) for up to 10 months.

Patient: Store below 25°C for up to 2 months. Store in the original package.

Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kisqali contains

- The active substance is ribociclib. Each film-coated tablet contains ribociclib succinate equivalent to 200 mg ribociclib.
- The other ingredients are:
Tablet core: microcrystalline cellulose; crospovidone type A; low-substituted hydroxypropylcellulose; magnesium stearate; colloidal anhydrous silica.
Coating material: iron oxide black (E172); iron oxide red (E172); soya lecithin (E322) (see

“Kisqali contains soya lecithin” in section 2); polyvinyl alcohol (partially hydrolysed); talc; titanium dioxide (E171); xanthan gum.

What Kisqali looks like and contents of the pack

Kisqali is supplied as film-coated tablets in blisters.

The film-coated tablets are light greyish violet in colour, unscored, round, debossed with “RIC” on one side and “NVR” on the other side.

The following pack sizes are available: Packs containing 21, 42 or 63 film-coated tablets and multipacks containing 63 (3 packs of 21), 126 (3 packs of 42) or 189 (3 packs of 63) film-coated tablets.

Kisqali packs containing 63 tablets are intended for use by patients taking the ribociclib daily dose of 600 mg (3 tablets once daily).

Kisqali packs containing 42 tablets are intended for use by patients taking the ribociclib daily dose of 400 mg (2 tablets once daily).

Kisqali packs containing 21 tablets are intended for use by patients taking the lowest ribociclib daily dose of 200 mg (1 tablet once daily).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novartis Pharmaceuticals UK Limited
2nd Floor, The WestWorks Building, White City Place
195 Wood Lane
London
W12 7FQ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Novartis Pharmaceuticals UK Ltd.
Tel: +44 1276 698370

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