

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
4. Possible side effects
5. How to store 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) inhibitors.

What Kisqali is used for

Kisqali is used in women with a type of breast cancer called hormone receptor-positive, human epidermal growth factor receptor (HER2)-negative breast cancer that is locally advanced or has spread to other parts of the body (metastatic). It 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.

How Kisqali works

Kisqali works by blocking proteins called cyclin-dependent kinases 4 and 6, which are important for the growth and division of cells. Blocking these proteins can slow down the growth of cancer cells and delay the progression of your 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 (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 medicines or supplements obtained without a prescription, because these may influence the effect of 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).

Make sure you tell your doctor of all medicines and supplements, including herbal medicines, that you are taking before you start treatment with Kisqali and if you are prescribed a new medicine after you have started treatment with Kisqali.

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

You should not eat grapefruits or drink grapefruit juice 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

- The recommended starting dose of Kisqali is 600 mg (3 tablets of 200 mg) once daily. 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, e.g. 400 mg (2 tablets of 200 mg) once daily or 200 mg (1 tablet of 200 mg) once daily.
- A treatment cycle lasts 28 days. Take Kisqali once a day only on days 1 to 21 of a 28-day 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. You should not take Kisqali on days 22 to 28 of the cycle.

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.

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.

This is a long-term treatment, possibly lasting for months or years. 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.

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

Stopping your treatment with Kisqali may cause your condition to get worse. Do not stop taking Kisqali unless your doctor tells you to.

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.

Some side effects could be serious

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).*

Your doctor may ask you to take a lower dose, interrupt your treatment with Kisqali, or stop it permanently.

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
- Shortness of breath, difficulty breathing
- Cough
- Nausea (feeling sick)
- Diarrhoea
- Vomiting
- Constipation
- Abdominal (belly) pain
- Mouth sores with gum inflammation (stomatitis)
- Upset stomach, indigestion, heartburn (dyspepsia)
- Hair loss or hair thinning (alopecia)
- Rash
- Itching (pruritus)
- Back pain
- Tiredness (fatigue)
- Swollen hands, ankles or feet (peripheral oedema)
- Fever (pyrexia)
- Weakness (asthenia)

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
- Spinning sensation (vertigo)
- Watering eyes
- Dry eyes
- Reduced level of potassium in the blood, which could lead to disturbance in heart rhythm
- Strange taste in the mouth (dysgeusia)
- Dry skin
- Skin reddening (erythema)
- Loss of skin colour in patches (vitiligo)
- Sore throat (oropharyngeal pain)
- Dry mouth
- Abnormal kidney blood test result (high level of creatinine in the blood)

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.

This medicine does not require any special storage conditions.

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 aluminum 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 full ribociclib daily dose of 600 mg (3 tablets once daily).

Kisqali packs containing 42 tablets are intended for use by patients taking the reduced 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.

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