KISQALI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Kisqali?

Kisqali contains the active ingredient ribociclib (as succinate). Kisqali is used to treat certain types of early and advanced or metastatic breast cancer.

For more information, see Section 1. Why am I using Kisqali? in the full CMI.

2. What should I know before I use Kisqali?

Do not use if you have ever had an allergic reaction to ribociclib, cyclin dependent kinase inhibitors, soy lecithin or any of the ingredients listed at the end of the CMI. Do not use Kisqali if you have a QT prolongation heart problem.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Kisqali? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kisqali and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Kisqali?

Kisqali is taken in repeating cycles of 28 days, once each day for 21 days followed by a 7 day treatment break. Kisqali is used in combination with a second medicine (either an aromatase inhibitor or fulvestrant), which are used as hormonal anticancer therapies.

- Early breast cancer: the usual starting dose is 400 mg (2 x Kisqali 200 mg tablets).
- Advanced or metastatic breast cancer: the usual starting dose is 600 mg (3 x Kisqali 200 mg tablets).

Your doctor will tell you exactly how many tablets to take. More instructions can be found in Section 4. How do I use Kisqali? in the full CMI.

5. What should I know while using Kisqali?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Kisqali. • Keep all your doctor appointments as regular tests on your blood, heart and lung function are needed.
Things you should not do	• Do not take Kisqali if you are pregnant or breastfeeding. • Do not eat grapefruit (or grapefruit juice), pomelo, star fruit or Seville oranges.
Driving or using machines	• Treatment with Kisqali may make you feel tired or dizzy.
Looking after your medicine	• Store the tablets in the refrigerator, at 2°C to 8°C.

For more information, see Section 5. What should I know while using Kisqali? in the full CMI.

6. Are there any side effects?

There can be serious side effects that need immediate medical attention. These include allergic reactions, severe skin reactions, fever or chills and frequent signs of infections, liver problems, chest pain or discomfort, shortness of breath.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

KISQALI®

Active ingredient: *ribociclib (as succinate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kisqali. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Kisqali.**

Where to find information in this leaflet:

1. Why am I using Kisqali?

Kisqali contains the active ingredient ribociclib. Kisqali is believed to work by blocking the effects of types of enzymes, called cyclin dependent kinases (CDK) that chemically signal cancer cells to grow and multiply. By blocking these enzymes, Kisqali may delay the growth of breast cancer.

Kisqali is used to treat patients with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)- negative breast cancer known as:

- **Early breast cancer:** localized 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 have certain characteristics that increase the risk of the cancer returning.
- **Advanced or metastatic breast cancer:** locally advanced or may also have spread to other parts of the body (metastatic).

2. What should I know before I use Kisqali?

Warnings

Do not take Kisqali if:

- **you are allergic to ribociclib, any cyclin dependent kinase inhibitor, soya lecithin, or any of the ingredients listed at the end of this leaflet.**

  Always check the ingredients to make sure you can use this medicine.

- **you have a heart problem known as QT prolongation.**

  This is caused by a change in the electrical activity of the heart, and is seen by your doctor on an ECG (electrocardiogram), or

- **you have conditions which put you at risk of getting QT prolongation,**
  such as: a slow heartbeat, low potassium, magnesium, calcium or phosphorous levels in your blood, a family history of QT prolongation, or
- **you take other medicines which prolong the QT interval.**

Women of child-bearing age who recently became postmenopausal or peri menopausal should not commence treatment with Kisqali until your post-menopausal status is fully established.

Check with your doctor if you:

- have any other medical conditions, including:
  - fever, sore throat or mouth ulcers due to infections (signs of low level of white blood cells)
  - problems with your liver or previously had any type of liver disease
  - heart failure, heart attack, heart disorders or heart rhythm disorders, such as an irregular heartbeat, including a condition called prolonged QT syndrome (QT interval prolongation)
  - low levels of potassium, magnesium, calcium, or phosphorous in your blood
- are still having periods
- take any other medicines or supplements.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Kisqali may harm your unborn baby if you are pregnant. **Women who are able to become pregnant should have a negative pregnancy test result before starting treatment and use effective birth control during treatment and for at least 21 days after stopping Kisqali.**

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if Kisqali is present in breast milk.

Your doctor will discuss with you the potential risks of taking Kisqali during pregnancy or when breast feeding.

Men taking Kisqali

Kisqali may reduce fertility in male patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Kisqali and affect how it works. In particular, these include medicines used to treat:

- fungal infections, such as ketoconazole, itraconazole, voriconazole or posaconazole
- bacterial infections, such as erythromycin, clarithromycin, azithromycin, moxifloxacin, levofloxacin, norfloxacin, and ciprofloxacin
- HIV/AIDS, such as: ritonavir, saquinavir, idinavir, lopinavir, nelfinavir, telaprevir and efavirenz
- seizures or fits, anti-epileptics such as carbamazepine, phenytoin, rifampin and midazolam
- heart rhythm problems, such as amiodarone, disopyramide, procainamide, quinidine and sotalol
- depression, anxiety, sleep problems, or other conditions with a herbal product called St John's Wort (also known as *Hypericum perforatum*).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Kisqali.

4. How do I use Kisqali?

Kisqali is taken in repeating cycles of 28 days (4 weeks). It is taken each day for 21 days, followed by a treatment break of 7 days when Kisqali tablets are not taken.

It is taken in combination with a second medicine (either an aromatase inhibitor or fulvestrant), which are used as hormonal anticancer therapies.

In women who have not reached menopause, and in men, when Kisqali is taken in combination with an aromatase inhibitor or fulvestrant, a third medicine from the group of luteinising hormone-releasing hormone (LHRH) agonists should also be taken. LHRH agonists reduce the amount of oestrogen or testosterone (a hormone) that is produced by your body.

How much to take

- **Days 1 to 21 (of repeating 28 day cycle)**
    - Early breast cancer: the usual starting dose is 400 mg (2 x Kisqali 200 mg tablets).
    - Advanced or metastatic breast cancer: the usual starting dose is 600 mg (3 x Kisqali 200 mg tablets).

Your doctor will tell you exactly how many tablets to take.

- **Days 22 to 28 (of repeating 28 day cycle)**
    - **Do not take any Kisqali tablets this week.**
    - The 7 day break when you do not take Kisqali tablets will help your body to recover and decrease the risks of getting any potentially serious side effects or an infection.
- Start taking Kisqali again the following week on days 1 to 21 as a new 28 day cycle begins.
- If you take Kisqali with an aromatase inhibitor, keep taking the aromatase inhibitor each day as directed by your doctor.

When to take Kisqali

- Kisqali should be taken once each day at about the same time each day, preferably in the morning on days 1 to 21 of a 28 day cycle.
- Kisqali tablet packs have a fifth flap under the main panel to help you keep track of your doses during each treatment cycle. Write in the days of the week starting with the first day of your treatment. Cross off a circle after each tablet that you take, in each week of the cycle, as shown in the pack example.

How to take Kisqali

Swallow Kisqali tablets whole with a glass of water or other liquid.

Do not chew, crush or split the tablets prior to swallowing.

Taking Kisqali in combination with an aromatase inhibitor, fulvestrant or LHRH agonist

These medicines are supplied separately. Your doctor will tell you how much and when to take the aromatase inhibitor or fulvestrant, and LHRH agonist if prescribed.

Keep taking theses medicines as directed by your doctor.

Taking with food or drinks

Kisqali tablets can be taken with or without food.

However, do not eat grapefruit (or drink grapefruit juice), pomelos, star-fruit, or Seville oranges during your treatment with Kisqali. These foods may change the way Kisqali is absorbed into your body.

How long to keep taking Kisqali

This is a long-term treatment, which may continue for many months or years.

Continue taking Kisqali once a day on days 1 to 21, of repeating 28 day cycles, for as long as your doctor tells you to. Your doctor will regularly check your condition to ensure that Kisqali treatment is having the desired effect on you.

If you forget to use Kisqali

Kisqali should be taken regularly at the same time each day on days 1 to 21.

If you miss a dose during days 1 to 21, skip the missed dose and take your next dose at your regular time on the next day.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering when to take or skip Kisqali, keep a treatment diary, or ask your doctor, nurse or pharmacist for some hints.

If you take too much Kisqali

If you think that you have taken too much Kisqali, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Kisqali?

Things you should do

Follow your doctor's instructions carefully. Your treatment may not help or you may have unwanted side effects if you do not follow the instructions.

Keep all your doctor's appointments to check your progress:

- You will have regular blood tests before and during treatment with Kisqali to monitor how your liver is working, the amount of blood cells, and electrolytes (blood salts including potassium, calcium, magnesium and phosphate) in your body.
- The electrical activity of your heart will be checked before and during treatment (with a test called an electrocardiogram or ECG). These tests can be affected by Kisqali.
- Your lung function will be checked.
- If necessary, additional tests to check how your kidneys are working will be done.

If necessary, your doctor may decide to stop Kisqali or reduce your Kisqali dose for a short time to allow your liver, kidneys, blood cells, electrolytes, lungs or heart activity to recover. Your doctor may also decide to stop treatment permanently**.**

Call your doctor straight away if you:

- Become pregnant – you should not take this medicine while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using Kisqali.

Things you should not do

- If you take Kisqali with an aromatase inhibitor, do not skip the aromatase inhibitor on any day. It must be taken every day as directed in the 28 day cycle
- Do not use Kisqali to treat any other complaint unless your doctor says you can
- Do not give this medicine to anyone else.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Kisqali affects you.

Kisqali may cause tiredness, dizziness or vertigo in some people.

Drinking alcohol

Be careful drinking alcohol until you know how Kisqali affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store Kisqali in the refrigerator, between 2°C to 8°C. Do not place in or too near the freezer section.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Very common side effects

Very common side effects	What to do
• Tiredness, fatigue, pale skin, feeling weak • Respiratory tract problems o Sore throat o Runny nose, blocked nose o Sneezing o Feeling of pressure or pain in the cheeks or forehead with or without fever, o Cough, hoarseness, weak voice or voice loss • Mouth, stomach or bowel problems o Reduced appetite o Nausea, vomiting o Diarrhea, constipation o Mouth sores or ulcers with gum inflammation o Stomach pain o Upset stomach, indigestion, heartburn o Painful and frequent urination • Back pain • Hair loss or thinning • Rash, itching • Headache • Swollen hands, ankles or feet • Dizziness or lightheadedness	**Speak to your doctor if you have any of these very common side effects and they worry you.**

Common side effects

Common side effects	What to do
• Mouth, stomach or bowel problems o Abdominal pain, nausea, vomiting, diarrhoea, swelling or bloating of the abdomen and feeling sick	**Speak to your doctor if you have any of these common side effects and**

Common side effects	What to do
o Strange taste in the mouth, dry mouth o Sore throat • Watering or tearing of the eyes, dry eye • Skin problems o Skin reddening o Loss of skin colour in patches o Dry skin.	**they worry you.**

Serious side effects

Serious side effects	What to do
• Allergic reactions o severe itching of the skin, with a red rash, or raised bumps; o swelling of the face, lips, tongue, throat, or other parts of the body; o difficulty in breathing or swallowing o dizziness. • Infections showing signs of: o fever, sweats 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, feeling very tired o fever, sore throat or mouth ulcers o increased heart rate, shortness of breath or rapid breathing, fever and chills (these may be signs of a sepsis which is an infection in the blood system which may be life threatening) • Heart problems o chest pain or discomfort o changes in heart beat (fast, slow or irregular), palpitations, o light headedness, fainting, dizziness o lips turning blue colour o shortness of breath o swelling (oedema) of your lower limbs or skin. • Severe skin reactions:	**Stop taking Kisqali and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
o blistering peeling skin with painful raw areas, fever, flu-like symptoms o rash, blisters or lesions. o Signs of liver problems o tiredness o itchy yellow skin or yellowing of the whites of your eyes o nausea or vomiting, loss of appetite o pain in the upper right side of the belly (abdomen) o dark or brown urine o bleeding or bruising more easily than normal. • Other serious side effects: o sore throat or mouth ulcers with a single episode of fever greater than 38.3°C, or above 38°C for more than one hour and/or with infection o shortness of breath, cough, anxiety, confusion and restlessness.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects can only be found when your doctor does tests to check your progress. It is very common for Kisqali to affect certain blood and liver function tests, and common for Kisqali to affect heart test results.

Your doctor will discuss with you what to do if any of your test results are affected.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Kisqali contains

Active ingredient (main ingredient)	Each tablet contains 200 mg ribociclib, as the succinate salt.

Other ingredients **(inactive ingredients)**	• Magnesium stearate (vegetable source) (E572) • Microcrystalline cellulose (E460(i)) • Hyprolose (E463) • Crospovidone (E1202) • Colloidal silicon dioxide • Polyvinyl alcohol (partially hydrolysed) (E1203) • Titanium dioxide (E171) • Iron oxide black CI77499 (E172) • Iron oxide red CI77491 (E172) • Iron oxide yellow CI77492 (E172) • Purified talc (E553b) • Lecithin (soy) (E322) • Xanthan gum (E415).
Potential allergens	Soy lecithin

Do not take this medicine if you are allergic to any of these ingredients.

Kisqali does not contain sucrose, lactose, gluten, tartrazine, azo dyes, or any animal products.

What Kisqali looks like

Kisqali film coated tablets are light greyish violet, unscored, round, curved with bevelled edges, debossed with "RIC" on one side and "NVR" on the other side (Aust R 280246).

The tablets are supplied in blister packs containing either 63, 42, or 21 tablets.

- 63 tablets: this pack is for patients taking 600 mg (as three 200 mg tablets) ribociclib once each day for 3 weeks. Each blister strip contains 21 tablets.
- 42 tablets: this pack is for patients taking 400 mg (as two 200 mg tablets) ribociclib once each day for 3 weeks. Each blister strip contains 14 tablets.
- 21 tablets: this pack is for patients taking the lowest ribociclib daily dose of 200 mg (one tablet) once each day. Each blister strip contains 7 tablets.

Who distributes Kisqali

Novartis Pharmaceuticals Australia Pty Limited

(ABN 18 004 244 160)

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Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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