

PART III: PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrKISQALI™
ribociclib tablets

Read this carefully before you start taking **KISQALI™** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **KISQALI**.

Your breast cancer will be treated with **KISQALI** in combination with letrozole. Read the letrozole Patient Medication Information leaflet carefully as well as this one.

Serious Warnings and Precautions

KISQALI should only be administered by a healthcare professional experienced in the use of anti-cancer drugs.

The following serious side effects have been seen in people taking KISQALI:

- **Heart problems:** chest pain or discomfort, heart palpitations, fast or slow heartbeat, dizziness, lightheadedness, fainting, sudden death
- **Liver problems:** itching, yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite
- **Low levels of white blood cells:** fever, sore throat, mouth ulcers or other signs of infections

What is **KISQALI** used for?

KISQALI is used for the treatment of postmenopausal women with a certain type of breast cancer that is advanced and may not be able to be removed by surgery or has spread to other parts of the body. **KISQALI** is to be used in combination with another medicine for breast cancer, called letrozole.

How does **KISQALI** work?

KISQALI belongs to a family of medications called kinase inhibitors. These medications work by stopping cancer cells from dividing and growing.

KISQALI has to be used together with another anti-cancer medicine called letrozole. When given together with letrozole, KISQALI may slow down the growth and spread of breast cancer cells.

What are the ingredients in KISQALI?

Medicinal ingredients: ribociclib succinate

Non-medicinal ingredients: Colloidal silicon dioxide; crospovidone (Type A); iron oxide black (E172); iron oxide red (E172); lecithin (soy) (E322); low-substituted hydroxypropylcellulose; magnesium stearate; microcrystalline cellulose; polyvinyl alcohol (partially hydrolysed); talc; titanium dioxide (E171); xanthan gum.

What KISQALI looks like and contents of the pack

KISQALI is supplied in aluminum blister packs.

The tablet is light greyish violet, unscored, round, curved with beveled edges, debossed with “RIC” on one side and “NVR” on the other side

KISQALI comes in the following dosage forms:

Tablets; 200 mg ribociclib (as ribociclib succinate)

Do not use KISQALI if you:

- are allergic (hypersensitive) to ribociclib succinate or to any of the other ingredients of KISQALI.
- have serious heart problems including a condition known as “congenital long QT syndrome”.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KISQALI. Talk about any health conditions or problems you may have, including if you:

- have fever, sore throat or mouth ulcers due to infections (signs of low level of white blood cells).
- have or have ever had any problems with your liver.
- have or have ever had heart problems, such as an irregular heartbeat, rate or rhythm, or low levels of potassium, magnesium, calcium or phosphorous in your blood.
- have a family history of sudden cardiac death.
- are dehydrated, suffer from persistent vomiting or an eating disorder.
- have diabetes.
- have a condition called “autonomic neuropathy” that causes problems with blood pressure, heart rate, sweating, bowel and bladder control and digestion.
- are pregnant, think you might be pregnant, or are planning to have a baby. KISQALI may harm

your unborn baby. If you are able to become pregnant, your healthcare professional will make sure that you are not pregnant before starting KISQALI. You must use effective birth control during treatment and for at least 21 days after stopping KISQALI. Ask your healthcare professional about ways to avoid becoming pregnant.

- are breast-feeding or plan to breast-feed. You should not breastfeed while you are taking KISQALI or for 21 days after your last dose.
- are taking any medicines or supplements.

Other warnings you should know about:

Your healthcare professional will do blood tests and a test to see how well your heart is working, called an electrocardiogram (ECG), before you start taking KISQALI and at regular intervals during your treatment.

Driving and Using Machines: KISQALI can cause fatigue and fainting. You should use caution when driving or operating potentially dangerous machinery while you are taking KISQALI.

During your treatment with KISQALI, tell your healthcare professional straight away:

- If you have fever, chills, weakness and frequent infections with signs such as, sore throat or mouth ulcers. This could be due to a low level of white blood cells.
- If you have tiredness, itchiness, yellow skin, nausea, vomiting, yellowing of the whites of your eyes, loss of appetite, pain in the abdomen, dark or brown urine, or more than normal bleeding or bruising. These could be signs of problems with your liver.
- If you have chest pain or discomfort, changes in heart beat (faster or slower), palpitations, if your lips turn blue, if you feel lightheaded, dizzy or faint, if you have trouble breathing, or if your skin or your legs swell. These could be signs of problems with your heart.

Children and adolescents (under 18 years old)

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

Fertility in male patients

KISQALI may reduce fertility in male patients.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

The following may interact with KISQALI:

- Some medicines used to treat infections. These include medicines which treat fungal infections, such as ketoconazole, itraconazole, fluconazole, voriconazole, amphotericin B and posaconazole, or medicines which treat certain types of bacterial infections, such as

telithromycin, clarithromycin, erythromycin, azithromycin, moxifloxacin, levofloxacin, ciprofloxacin and pentamidine

- Some medicines used to treat malaria such as quinine and chloroquine
- 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, phenytoin, rifampin and midazolam
- St. John's Wort, an herbal product used to treat depression and other conditions (also known as *hypericum perforatum*)
- Some medicines used to treat heart rhythm problems such as amiodarone, disopyramide, procainamide, quinidine, sotalol, ibutilide, dronedarone, flecainide and propafenone
- Some medicines used to treat heart problems such as ivabradine, beta-blockers, digitalis glycosides, non-dihydropyridine calcium channel blockers, cholinesterase inhibitors, alpha2-adrenoceptor agonists, Ir inhibitors and sphingosine-1 phosphate receptor modulators
- Some medicines used to treat high blood pressure such as verapamil and loop, thiazide and other diuretics (“water pills”)
- Some medicines used to treat mental health problems such as olanzapine, chlorpromazine, pimozide, haloperidol, droperidol and ziprasidone
- Some medicines used to treat depression such as fluoxetine, citalopram, venlafaxine, amitriptyline, imipramine and maprotiline
- Some medicines used to treat migraines such as dihydroergotamine and ergotamine
- Some anesthetics used during surgery and pain medicines such as alfentanil, fentanyl and methadone
- Some medicines used to suppress the immune system in people who have had organ transplants such as cyclosporine, everolimus, sirolimus and tacrolimus
- Some medicines used to treat cancer such as ondansetron, sunitinib, nilotinib, ceritinib, vandetanib, arsenic trioxide and vorinostat
- Some medicines used to treat breathing problems, like asthma, such as salmeterol and formoterol
- Domperidone used to increase milk supply in breastfeeding mothers
- Anagrelide used to treat high levels of blood platelets
- Corticosteroids used to treat swelling and to suppress the immune system
- Proton Pump Inhibitors (PPIs) used to treat heartburn
- Laxatives and enemas
- Do not eat pomegranates, drink pomegranate juice, eat grapefruits or drink grapefruit juice while you are taking KISQALI.

You should also tell your healthcare professional if you are already taking KISQALI and you are prescribed a new medicine that you have not taken before.

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

How to take KISQALI:

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

Do not take more pills than the number prescribed by your healthcare professional.

You should not eat grapefruit or pomegranate or drink grapefruit or pomegranate juice while you are taking KISQALI. They may increase the amount of KISQALI in your blood and affect how KISQALI works.

- You should take KISQALI once daily, for 21 consecutive days. This is followed by 7 days off-treatment.
- Taking KISQALI at the **same time of day** will help you to remember when to take it. It is better to take KISQALI in the morning.
- KISQALI tablets should be **swallowed whole** (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be taken if it is broken, cracked, or otherwise not intact.
- KISQALI tablets can be taken with or without food.
- KISQALI tablets should be taken in combination with letrozole. Your healthcare professional will tell you exactly how many tablets of KISQALI to take and the dose of letrozole you should take and also when you should take it.

It is very important to follow your healthcare professional's advice. If you have certain side effects, your healthcare professional may ask you to take less medicine, to skip a dose or to stop treatment.

Usual starting dose:

600 mg orally (3 tablets of 200 mg) taken once daily for 21 consecutive days followed by 7 days off-treatment.

Continue taking KISQALI for as long as your healthcare professional tells you to. This is a long-term treatment, possibly lasting for months or years. Your healthcare professional will regularly monitor your condition to check that the treatment is working.

Overdose:

If you think you have taken too much KISQALI, or if someone else accidentally takes your medicine, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms. Show the KISQALI packet. Medical treatment may be necessary.

Missed Dose:

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

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

If you stop taking KISQALI:

Stopping your treatment with KISQALI may cause your condition to become worse. Do not stop taking KISQALI unless your healthcare professional tells you to stop.

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

What are possible side effects from using KISQALI?

These are not all the possible side effects you may feel when taking KISQALI. If you experience any side effects not listed here, contact your healthcare professional.

Some side effects are very common

- Reduced appetite
- Shortness of breath, labored breathing
- Back pain
- Nausea
- Diarrhea
- Vomiting
- Constipation
- Mouth sores or ulcers with gum inflammation
- Abdominal pain
- Hair loss or hair thinning
- Rash
- Itching
- Tiredness (fatigue)
- Weakness
- Fever
- Headache
- Difficulty falling asleep
- Swollen hands, ankles or feet (edema)

Some side effects are common

- Watering or tearing of eyes
- Dry eye
- Nose bleeds
- Strange taste in the mouth

- Upset stomach, indigestion
- Skin reddening
- Decreased weight

KISQALI can cause abnormal blood test results (such as an increase in creatinine or low levels of phosphate). Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Low levels of white blood cells: fever, sore throat or mouth ulcers due to infections			√
Liver problems: itchiness, yellow skin, nausea, vomiting, yellowing of the whites of your eyes, loss of appetite, pain in the abdomen, dark or brown urine, or more than normal bleeding or bruising.			√
Anemia (low levels of red blood cells): fatigue, loss of energy, weakness, shortness of breath		√	
Urinary tract infection: pain and/or burning when urinating, blood in the urine, increased urge to urinate		√	
COMMON Low levels of platelets: spontaneous bleeding or bruising			√
Febrile neutropenia: sore throat or mouth ulcers with a single episode of fever >38.3°C (or) above 38°C for more than one hour and/or with infection			√

Low levels of potassium in the blood: irregular heartbeat, muscle weakness			√
Low levels of calcium in the blood: muscle cramps and spasms, numbness and tingling in the hands, feet and face			√
Fainting (syncope)			√
Heart problems: irregular heart beat (change in the electrical activity of the heart which may cause sudden death), chest pain or discomfort, dizziness, palpitations			√
UNCOMMON Blood clot in the lung: sudden, severe chest pain and trouble breathing, coughing up blood, rapid breathing and heartbeat			√
UNKNOWN FREQUENCY Serious allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on <u>Adverse Reaction Reporting</u> (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>

Storage:

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

- Do not take this medicine after the expiry date, which is stated on the box.
- Do not store above 30°C. Store in the original packaging to protect from moisture.
- Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Ask your pharmacist how to dispose of medicines you no longer use.

If you want more information about KISQALI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://www.canada.ca/en/health-canada.html) (<http://www.canada.ca/en/health-canada.html>); the manufacturer's website (<http://www.novartis.ca>) or by calling 1-800-363-8883.

KISQALI is a trademark.

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