

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **KISQALI**[®]

ribociclib tablets

This Patient Medication Information is written for the person who will be taking **KISQALI**[®]. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **KISQALI**, talk to a healthcare professional.

Your breast cancer may be treated with **KISQALI** in combination with another drug (aromatase inhibitors or fulvestrant). Read the Patient Medication Information for the other drug as well as this one.

Serious warnings and precautions box

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 KISQALI is used for:

KISQALI is used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer including:

- early breast cancer. This means the cancer is 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 has certain characteristics that increase the risk of the cancer returning. KISQALI is used in combination with an aromatase inhibitor, which is used as hormonal anticancer therapy to prevent the cancer from coming back after surgery.
- advanced or metastatic breast cancer. This means the cancer has grown outside the breast and spread to the lymph nodes in the area of the breast (locally advanced) or has spread to other parts of the body (metastatic). KISQALI is used in combination with the following when treating advanced or metastatic breast cancer:
 - an aromatase inhibitor as the first endocrine-based therapy; or
 - fulvestrant as the first endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

How KISQALI works:

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 an aromatase inhibitor or with fulvestrant. When given together with one of these drugs, KISQALI may slow down the growth and spread of breast cancer cells.

The ingredients in KISQALI are:

Medicinal ingredient: ribociclib succinate

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

KISQALI comes in the following dosage form:

Tablets; 200 mg ribociclib (as ribociclib succinate)

Do not use KISQALI if:

- you are allergic to ribociclib succinate or to any of the other ingredients of KISQALI.
- you have serious heart problems including a condition known as “congenital long QT syndrome” or at significant risk of developing QT prolongation.

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 or kidneys.
- 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 taking any medicines or supplements.

Other warnings you should know about:**Pregnancy, breast-feeding and fertility**

- If you are pregnant, still able to get pregnant, or think you are pregnant, there are specific risks you must discuss with your healthcare professional.
- Avoid becoming pregnant while taking KISQALI. It 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.
- Use effective birth control if you can get pregnant while taking KISQALI and for at least 21 days after your last dose. Ask your healthcare professional about ways to avoid becoming pregnant.
- You should not breastfeed while you are taking KISQALI or for 21 days after your last dose.

Fertility in male patients

- KISQALI may reduce fertility in male patients, which may affect your ability to father a child. Talk to your healthcare professional if this is a problem for you.

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.

Monitoring and tests: Before starting treatment and periodically during your treatment, your healthcare professional will perform:

- Electrocardiography. This measures the electrical activity of your heart.
- Blood tests for:
 - electrolyte levels (including potassium, calcium, phosphorus and magnesium)
 - blood cell levels
 - liver function

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.
- If you have trouble breathing, cough and shortness of breath. Tell your healthcare professional right away if you experience new or worsening symptoms. These could be signs of serious lung problems (pneumonitis/interstitial lung disease) during treatment that can lead to death.
- 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 serious skin reaction). **Tell your doctor immediately if you experience new or worsening symptoms**

Children and adolescents (under 18 years old)

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

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

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, If 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 grapefruits or drink grapefruit juice while you are taking KISQALI.
- Some medicines used to treat high cholesterol levels (statins), such as simvastatin, lovastatin and atorvastatin.

Know the medicines you take. Keep a list of them to show your healthcare professional.

Ask your healthcare professional if you are not sure whether your medicine is one of the medicines listed above.

You should also tell your healthcare professional if you are prescribed a new medicine while taking KISQALI.

How to take KISQALI:

Take KISQALI exactly as prescribed for you by your healthcare professional. They will tell you exactly how many tablets to take along with the other drugs and which days to take them on. Check with your healthcare professional 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.

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.

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.

You should not eat grapefruit or drink grapefruit 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.

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 dose:

KISQALI in early breast cancer: 400 mg orally (2 tablets of 200 mg) taken once daily for 21 consecutive days followed by 7 days off-treatment.

KISQALI in advanced or metastatic breast cancer: 600 mg orally (3 tablets of 200 mg) taken once daily for 21 consecutive days followed by 7 days off-treatment.

Overdose:

If you think that you or a person you are caring for have taken too much KISQALI, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you vomit after taking your dose, do not take an additional dose. If you miss a dose, discard the tablets for that missed dose. Take your next dose at your regular time the following day until your 21-

day treatment is completed. Do not replace a missed dose on subsequent days to avoid affecting the 7 days off treatment.

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.

- A sensation of losing balance
- Constipation
- Cough
- Dehydration
- Diarrhea
- Dizziness or light headedness
- Dry eyes, mouth or skin
- Eyes: Watering or tearing of eyes; blurry vision, irritated eyes, swelling and redness of the inside of the eyelid (pink eye)
- Fever
- Hair loss or hair thinning
- Headache
- Itching
- Loss of skin color in patches (vitiligo)
- Mouth sores or ulcers with gum inflammation
- Nausea, vomiting
- Pain: abdominal, back, neck, head
- Rash
- Reduced appetite
- Shortness of breath, labored breathing
- Skin reddening
- Sore throat
- Strange taste in the mouth
- Swollen hands, ankles or feet
- Tiredness
- Trouble sleeping
- Upset stomach, indigestion
- Weakness

KISQALI can cause abnormal blood test results and changes in the electrical signal of the heart. Your healthcare professional will do some tests before and during your treatment. They will tell you if your test results are abnormal and if you need treatment.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Anemia (low levels of red blood cells): fatigue, loss of energy, weakness, shortness of breath, pale skin		√	
Gastroenteritis (infections of the stomach and intestines): Abdominal pain, diarrhea, nausea and vomiting			√
Infections: Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, diarrhea or stomach pain, warm or painful areas on your body, or feeling very tired			√
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			√
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath			√
Urinary tract infection: pain and/or burning when urinating, blood in the urine, increased urge to urinate		√	
Common			
Depression (feelings of sadness or hopelessness that lasts for a long time)		√	
Fainting (syncope)			√
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			
Heart problems: chest pain or discomfort, heart palpitations, fast or slow heartbeat, dizziness, lightheadedness, fainting, sudden death			√
Prolongation of QT interval (Changes in the electrical system of your heart): Irregular heartbeat, fainting, loss of consciousness, seizures			√
Respiratory tract infections: runny or stuffy nose, sore throat, cough, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell		√	
Low levels of calcium: muscle cramps and spasms, numbness and tingling in the hands, feet and face			√
Low levels of platelets: spontaneous bleeding or bruising			√
Low levels of potassium: irregular heartbeat, muscle weakness			√
Vertigo (a sense of spinning dizziness)		√	
Uncommon			
Pulmonary embolism (blood clot in the lung): sudden, severe chest pain and trouble breathing, coughing up blood, rapid breathing and heartbeat			√
Sepsis and septic shock (infection of the blood): fever or dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat			√
Unknown			
Pneumonitis/ Interstitial lung disease (inflammation of the lung tissue): Trouble breathing, cough and shortness of breath, fever, feeling tired			√

<p>Severe skin reaction that might include a combination of: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (toxic epidermal necrolysis (TEN))</p>			<p>✓</p>
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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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

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.
- Store your medication between 15 °C and 25°C
- Store in 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 healthcare professional 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 the Patient Medication Information by visiting the Health Canada Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website (<http://www.novartis.ca>) or by calling 1-800-363-8883.

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KISQALI is a registered trademark.

