

## Medication Information Sheet

**ribociclib** (rye-boe-SYE-klib)

*This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.*

**Other Name:** Kisqali™

**Appearance:** Tablet.

**What is this medication for?**

For treating advanced breast cancer that may not be able to be removed by surgery or has spread to other parts of the body, in combination with another medication

**What should I do before I have this medication?**

Tell your health care team:

- If you have or had significant medical condition(s), such as:
  - Diabetes
  - Electrolyte problems (like calcium, magnesium, phosphorous, or potassium)
  - Heart problems, an irregular heartbeat or heart rate
  - Liver problems
- A family history of sudden cardiac death.
- If you have an eating disorder, are following a strict diet or have conditions that could lead to changes of salt levels in your blood (severe vomiting, diarrhea, dehydration, kidney problems).
- Any allergies.

People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.

## How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, become(s) pregnant during treatment, or if you are breastfeeding.
- If there is **any chance** that you or your partner may become pregnant, you and your partner together must:
  - **Use 2 effective forms of birth control** at the same time while taking this drug.
  - Do not use hormone-based birth control (e.g. pills, vaginal rings) if you have breast cancer.
  - Keep using birth control methods for at least **3 weeks** after your last dose. Talk to your healthcare team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using this drug and for at least **3 weeks** after treatment ends.
- This medication may affect fertility (ability to get pregnant).

## How is this medication given?

- Ribociclib is preferably taken in the morning, **once a day by mouth for 21 days followed by a one week break** with no ribociclib treatment.
- Tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing) with a glass of water.
- Tablets can be taken with or without food.
- If you miss a dose, skip this and take your next dose as you normally do. Do not take an extra dose to make up for the missed dose.
- Ribociclib is usually taken with another medication, for example, letrozole, anastrozole or exemestane. Your healthcare professional will tell you exactly how many tablets of ribociclib and the other medication to take and also when you should take them.

## What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping

any of them.

- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.
- Do not eat or drink grapefruit, starfruit, seville oranges, pomegranate or their juices (or products that contain these) while on this treatment. They may increase side effects.
- Exercise caution when driving or operating dangerous machinery while you are taking this drug as it can cause fatigue and fainting.

For mild aches and pain or fever:

- If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
- You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
- Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
- **Talk to your health care team or go to the closest emergency room right away if you have a fever. See the [Fever](#) pamphlet for more information**

## How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.

## What are the side effects of this medication?

Side effects and what to do	When to contact doctor?
<b>Very Common Side Effects (in 50 or more out of 100 people)</b>	
<p><b>Low platelets in the blood</b></p> <ul style="list-style-type: none"> <li>• Watch for bleeding (such as unusual nosebleeds or bleeding from the gums) or bruising easily (this is rare).</li> <li>• Very rarely, severe symptoms can happen. If you notice black coloured stools (poo), red or pink coloured urine (pee), red or brown coloured mucus when you cough, severe headache/confusion or bleeding that will not stop, you need to talk to your health care team or go to the nearest emergency room right away.</li> </ul> <p>See the <a href="#">Low Platelet Count</a> pamphlet for more information.</p> <p><b>Fever, chills, infection</b></p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> <li>• <b>38.3°C (100.9°F) or higher at any time OR</b></li> <li>• <b>38.0°C (or 100.4°F) or higher for at least one hour.</b></li> </ul> <p>While you are getting treatment:</p> <ul style="list-style-type: none"> <li>• Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills).</li> <li>• Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever.</li> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> <li>• Wash your hands often to prevent infection.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> </ul> <p><b>If you have a fever, talk to your health care team or go to the closest emergency room.</b></p> <p>See our <a href="#">Neutropenia (Low white blood cell count)</a> pamphlet for more information.</p>	<p>Get emergency medical help right away</p>

Side effects and what to do	When to contact doctor?
<b>Very Common Side Effects (in 50 or more out of 100 people)</b>	
<p><b>Nausea and vomiting (generally mild)</b></p> <p>May occur in hours to days after your treatment.</p> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take anti-nausea medication(s) as prescribed to you by your doctor.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (e.g. coffee, tea) and alcohol.</li> <li>• Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting.</li> </ul> <p>Also see <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</p>	<p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p>

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (in 25 to 49 out of 100 people)</b>	
<p><b>Abnormal liver lab tests</b></p> <ul style="list-style-type: none"> <li>• You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens.</li> <li>• Your doctor may monitor your liver regularly with a blood test.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Fatigue (tiredness)</b></p> <ul style="list-style-type: none"> <li>• Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise.</li> <li>• Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>• Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less).</li> <li>• Avoid driving or using machinery if you are feeling tired</li> </ul> <p>See our <a href="#">Fatigue</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (in 25 to 49 out of 100 people)</b>	
<p><b>Diarrhea</b></p> <p>May happen days to weeks after you get your treatment.</p> <p><b>If you have diarrhea :</b></p> <ul style="list-style-type: none"> <li>• Take anti-diarrhea medication if your health care team prescribed it.</li> <li>• Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol.</li> <li>• Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>• Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy.</li> </ul> <p>See the <a href="#">Diarrhea</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Hair thinning or loss</b></p> <ul style="list-style-type: none"> <li>• Use a gentle soft brush and avoid hair sprays, bleaches, dyes and perms.</li> <li>• In most cases, your hair will grow back after treatment, but the texture or colour may change.</li> </ul>	<p>Talk to your health care team if this bothers you</p>
<p><b>Constipation</b></p> <p><b>To help prevent constipation :</b></p> <ul style="list-style-type: none"> <li>• Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise.</li> <li>• Be Active. Exercise can help to keep you regular.</li> <li>• Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you.</li> </ul> <p><b>To help treat constipation :</b></p> <ul style="list-style-type: none"> <li>• If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do.</li> </ul> <p>See the <a href="#">Constipation</a> Pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (in 10 to 24 out of 100 people)</b>	
<p><b>Headache; mild joint, muscle pain or cramps</b></p> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medications may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Abnormal kidney lab tests</b></p> <ul style="list-style-type: none"> <li>• Signs of a kidney problem include swelling, passing very little or no pee, or new unusual weight gain. If you have these signs, call your health care team or go to your closest emergency department.</li> <li>• To prevent bladder or kidney problems, drink lots of water or other liquids. Your doctor may ask you to drink at least 6 to 8 cups (2 L) per day on treatment days, unless you have been told otherwise.</li> <li>• Your doctor may check your kidney function regularly.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Rash; dry, itchy skin</b></p> <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p> <p><b>To prevent and treat dry skin,</b></p> <ul style="list-style-type: none"> <li>• Use skin moisturizer.</li> <li>• Protect your skin from the sun and the cold.</li> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Low appetite</b></p> <ul style="list-style-type: none"> <li>• You may not feel like eating or you may lose weight.</li> <li>• Try to eat foods that you like and eat small meals throughout the day.</li> <li>• You may need to take meal supplements to help keep your weight up.</li> <li>• Talk to your health care team if you have a low appetite.</li> <li>• See our <a href="#">Loss of appetite</a> pamphlet for more information.</li> </ul>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (in 10 to 24 out of 100 people)</b>	
<p><b>Mild swelling in arms and legs; puffiness</b></p> <p><b>To help prevent swelling :</b></p> <ul style="list-style-type: none"> <li>• Eat a low-salt diet.</li> <li>• Avoid tight fitting clothing.</li> </ul> <p><b>If you have swelling in your legs, keep your feet up when sitting.</b></p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Salt imbalances</b></p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	<p>Get emergency medical help right away</p>
<p><b>Short of breath, difficulty breathing</b></p>	<p>Get emergency medical help right away</p>
<p><b>Trouble falling asleep</b></p> <ul style="list-style-type: none"> <li>• This may be caused by one of your medications and may improve once your body gets used to the medication or when your treatment ends.</li> <li>• Talk to your doctor if this bothers you.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Mouth sores</b></p> <p>You may have round, painful, white or gray sores inside your mouth. They can occur on the tongue, lips, gums, or inside your cheeks. In more severe cases they may make it hard to swallow, eat or to brush your teeth. They usually last 1 to 2 weeks.</p> <p><b>To help prevent mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Take care of your mouth by gently brushing and flossing regularly.</li> <li>• Rinse your mouth often. Do not use mouthwashes with alcohol.</li> <li>• Instead, try a homemade mouthwash:</li> <li>• Mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water.</li> </ul>	<p>Contact your health care team as soon as possible</p>



Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (in 10 to 24 out of 100 people)</b>	
<p><b>If you have mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Check with your health care team as soon as you notice mouth or lip sores or if it hurts to swallow.</li> <li>• Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a mouthwash to relieve mouth sores and prevent infection.</li> </ul> <p>See the <a href="#">Mouth Care</a> pamphlet for more information.</p>	
<p><b>Pains or cramps in the belly</b></p> <ul style="list-style-type: none"> <li>• If you have constipation or diarrhea it may be causing the pain in your belly.</li> <li>• If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

**Other rare, but serious side effects are possible. If you experience ANY of the following, speak to your health care provider or get emergency medical help right away:**

- Irregular heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly.
- Sudden, severe chest pain and trouble breathing, coughing up blood, rapid breathing and heartbeat.

For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://www.cancercareontario.ca/symptoms).

*The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.*

*A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*