

ORAL CANCER TREATMENT EDUCATION



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RIBOCICLIB

Name of your medication

Generic name — ribociclib (RY-boh-SY-klib)
Brand name — Kisqali® (kis-Kah-lee)

Common uses

Ribociclib is used in combination with an aromatase inhibitor or fulvestrant to treat hormone receptor–positive (HR+) or human epidermal growth factor receptor 2–negative (HER2-) advanced or metastatic breast cancer. It is used in combination with an aromatase inhibitor to treat HR+, HER2- stage II and III early breast cancer at high risk for recurrence.

Ribociclib may also be used for other treatments.

Dose and schedule

Taking ribociclib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- ❑ Your dose may vary, but the usual dose of ribociclib is 600 milligrams (600 mg) to be taken by mouth once daily for 21 consecutive days followed by 7 days off treatment.
- ❑ Dosage for early-stage breast cancer is typically 400 milligrams (400 mg) to be taken by mouth once daily for 21 consecutive days followed by 7 days off treatment.
- ❑ Ribociclib can be taken with or without food, at the same time each day, preferably in the morning.
- ❑ Ribociclib should be taken whole and not crushed, cut, opened, or dissolved. If you are unable to swallow ribociclib, talk to your care provider or pharmacist for possible options.
- ❑ If you miss a dose of ribociclib, **do not** take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- ❑ Ribociclib has many drug interactions, please inform your care provider of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- ❑ Grapefruit, pomegranate, grapefruit juice, or pomegranate juice may interact with ribociclib; avoid eating or drinking these during treatment with ribociclib.
- ❑ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle ribociclib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ❑ Store ribociclib at room temperature (68°F–77°F) in a dry location away from light for up to 2 months.
- ❑ Keep ribociclib out of reach of children and pets.

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- ❑ Leave ribociclib in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, you should give ribociclib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give ribociclib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the ribociclib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- ❑ A daily pill box or pill reminder is **not** recommended to be used with ribociclib.
- ❑ If you have any unused ribociclib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of ribociclib.
- ❑ If you are traveling, put your ribociclib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Ribociclib

Below are common side effects that have been known to happen in about one third or more of patients taking ribociclib; they are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect

Management

Decreased white blood cells (WBCs) and increased risk for infection

Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.

- Wash your hands often, especially before eating and after using the bathroom.
- Avoid crowds and people with fevers, flu, or other infection.
- Bathe regularly to keep good personal hygiene.

Contact your care provider if you experience any signs or symptoms of an infection such as:

- Fever (temperature more than 100.4°F or 38°C)
- Chills
- Sore throat
- Burning with urination
- Unusual tiredness
- A sore that becomes red, is draining, or does not heal

Check with your care provider before taking any medicine for a fever or chills.

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Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is OK to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
<p>Changes in liver function</p>	<p>Your liver function should be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Unusual bleeding or bruising
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is OK to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
Hair loss (alopecia)	<p>Your hair will grow back after treatment is over.</p> <p>Some people choose to wear scarves, caps, or wigs. A short haircut prior to treatment may help with stress of hair loss.</p>

Serious side effects of ribociclib

- ❑ Be aware of changes in the electrical activity of your heart, called QT prolongation. Tell your healthcare provider right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast, while taking ribociclib.
- ❑ Ribociclib may cause harm to your lungs. Inform your care team of any new or worse difficulty breathing, cough, shortness of breath, chest pain, or fever. Your provider may stop treatment if your lungs are affected.
- ❑ Ribociclib may cause a severe skin reaction resulting in flu-like symptoms and painful rashes that can spread and blister. Your healthcare professional may withhold or permanently discontinue medication depending on the severity.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Since ribociclib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take ribociclib, it is important to know the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or ribociclib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking ribociclib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 3 weeks after the last dose of ribociclib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking ribociclib and for 3 weeks after the last dose of ribociclib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about the process for obtaining your ribociclib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: www.us.kisqali.com/metastatic-breast-cancer

Product prescribing information: https://www.novartis.com/us-en/sites/novartis_us/files/kisqali.pdf

Product resources: www.us.kisqali.com/metastatic-breast-cancer/patient-support/financial-resources

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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