

Ribociclib (Kisqali)

About This Medicine

Ribociclib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Tiredness
- Changes in your liver function
- Blood sugar levels may change
- Headache
- Back pain
- Changes in your kidney function
- Cough
- Infection
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with ribociclib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Abnormal electrocardiogram (EKG/ECG)
- Severe allergic skin reaction. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.

- Inflammation (swelling) and/or scarring of the lungs which can be life-threatening. You may have a cough and/or trouble breathing.
- Severe changes in your liver function
- Decrease in the number of white blood cells including neutropenic fever, a type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

How to Take Your Medicine

- Swallow the medicine whole with or without food. Take your medicine at approximately the same time every day it is scheduled, preferably in the morning. Do not crush, chew, or split tablets.
- Do not take your medicine if tablets look cracked, broken or look damaged.
- **Missed Dose:** If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have unused medicine take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.



- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature.
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation, diarrhea and/or nausea/vomiting.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise levels of ribociclib in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with ribociclib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking ribociclib as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Tiredness that interferes with your daily activities
- Easy bleeding or bruising



- Feeling dizzy or lightheaded
- Feeling that your heart is beating fast or not in a normal way (palpitations)
- Dry cough or a cough that is bothersome
- Wheezing and/or trouble breathing
- Pain in your chest
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- Decreased or very dark urine
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Pain that does not go away, or is not relieved by prescribed medicines
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you are pregnant

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 3 weeks after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 3 weeks after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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