

# Ribociclib (Kisqali®)

Pronounce: rye-boe-SYE-klib

Classification: kinase inhibitor

### About Ribociclib (Kisqali®)

Ribociclib is a kinase inhibitor. It affects the growth and spread of cancer cells by inhibiting cyclin-dependent kinase 4 (CDK4) and cyclin-dependent kinase 6 (CDK6), proteins in the nucleus (center) of the cell that tell the cell to grow and divide. In some cancers, these proteins are overactive, causing cells to grow and divide too fast. By inhibiting these proteins, this medication can slow or stop cell growth and division of cancer cells.

#### How to Take Ribociclib

Ribociclib is taken by mouth, in tablet form, and can be taken with or without food. It should be taken around the same time each day, preferably in the morning. If you vomit after taking a dose or forget to take a dose, do not take another dose on that day. Take your next dose at your regular time.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. Foods to avoid include pomegranate, pomegranate juice, grapefruit and grapefruit juice. This medication can also interact with medications that prolong the QT interval. Speak to your provider about all medications, including those that are prescribed or over the counter medications, vitamins, and supplements you are taking.

Prior to starting this medication, you will have an electrocardiogram done and lab work to check your complete blood count and liver function. These tests will be repeated throughout your treatment with this medication.

# Storage and Handling

Store your medication in the original, labeled blister pack in the refrigerator, or at room temperature for up to 2 months and in a dry location (unless told to do otherwise by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pouring the pills directly from the container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

# Where do I get this medication?

Ribociclib is available through retail or mail order pharmacy. Your oncology team will work with your prescription drug plan to identify an in-network, retail or mail order pharmacy for medication distribution.

#### Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which lower the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

#### Possible Side Effects of Ribociclib

There are a number of things you can do to manage the side effects of ribociclib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

#### Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication can cause life threatening infections, with or without a decrease in white blood cell counts. White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

#### Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

#### Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell countan is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

### **Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

### **Renal Toxicity**

This medication can cause kidney toxicity, which your doctor may monitor for using blood tests to check your creatinine level. Notify your healthcare provider if you notice decreased urine output, blood in your urine, swelling in the ankles, or loss of appetite.

### Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

#### Diarrhea

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, uncaffeinated fluid a day to prevent dehydration.

#### Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all overthe-counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

### **Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

# Muscle, Back or Joint Pain/Aches and Headache

Your healthcare provider can recommend medications and other strategies to help relieve pain.

# Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

# Loss or Thinning of Scalp and Body Hair (Alopecia)

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

#### Low Blood Sugar (Hypoglycemia)

Your care team will monitor your blood levels, include blood sugar. Diabetic patients may need to monitor their glucose more often and/or change their diabetes medication. Signs of low blood sugar can be shakiness, fast heartbeat, dizziness, increased hunger, sweating, and confusion. Call your care team if you are having any of these symptoms.

#### Important but Less Common Side Effects

- *Heart Problems:* This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Notify your healthcare provider right away if you feel abnormal heartbeats or if you feel dizzy or faint. Prior to starting treatment with this medication, you will have an electrocardiogram (ECG) performed to check for an abnormal heart rhythm. You will have another ECG done on day 14 of the first cycle of treatment, at the beginning of the second cycle, and then at your provider's discretion. You will also have lab work drawn to monitor electrolytes at the beginning of each cycle, for 6 cycles, and then as needed.
- **Lung Inflammation:** In rare cases, this medication can cause inflammation of the lungs which can lead to interstitial lung disease or pneumonitis. If you have a new cough (with or without mucous), trouble breathing, shortness of breath or chest pain, call your provider right away.
- **Severe skin reactions:** If you have a severe rash or rash that keeps getting worse, reddened skin, flulike symptoms, skin pain/burning, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever you should call your provider right away.

### Sexual and Reproductive Concerns

This medication may affect a man's reproductive system, resulting in sperm production becoming irregular or stopping permanently. Your desire for sex may decrease during treatment. You may want to consider sperm banking if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 3 weeks after treatment is stopped. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should consult with your healthcare team before breastfeeding while receiving this medication. You should not breastfeed while receiving this medication and for at least 3 weeks after the last dose.

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