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Ribociclib: Patient drug information

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(For additional information see "Ribociclib: Drug information")

Brand Names: US Kisqali 200 Dose; Kisqali 400 Dose; Kisqali 600 Dose

What is this drug used for?

It is used to treat a type of breast cancer.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to this drug or any part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- · If you have any of these health problems: Electrolyte problems (like calcium, magnesium, phosphorous, or potassium), heart problems like heart failure or a certain type of chest pain (unstable angina), long QT on ECG, or slow or abnormal heartbeat.
- If you have had a recent heart attack.
- If you are taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT) interval). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, or seizures. There are many drugs that must not be taken with this drug.
- If you are taking St. John's wort. Do not take St. John's wort with this drug. This drug may not work as well.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 3 weeks after your last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- An unsafe heartbeat that is not normal (long QT on ECG) has happened with this drug. This may raise the chance of sudden death. Talk with the doctor.
- You will need an ECG before starting this drug and during treatment. Talk with your doctor.
- If you have upset stomach, throwing up, loose stools (diarrhea), or are not hungry, talk with your doctor. There may be ways to lower these side effects.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Avoid star fruit, pomegranate or pomegranate juice, and grapefruit or grapefruit juice while you take this drug.
- This drug may affect how much of some other drugs are in your body. If you are taking other drugs, talk with your doctor. You may need to have your blood work checked more closely while taking this drug with your other drugs.
- This drug may affect being able to father a child. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.
- Use birth control that you can trust to prevent pregnancy while taking this drug and for at least 3 weeks after your last dose.
- If you get pregnant while taking this drug or within 3 weeks after your last dose, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of electrolyte problems like mood changes, confusion, muscle pain or weakness, a heartbeat that does not feel normal, seizures, not hungry, or very bad upset stomach or throwing up.
- Dizziness or passing out.
- A fast heartbeat.

- A heartbeat that does not feel normal.
- Feeling very tired or weak.
- Shortness of breath.
- · Swelling in the arms or legs.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Upset stomach or throwing up.
- · Feeling tired or weak.
- Loose stools (diarrhea).
- Hard stools (constipation).
- Not hungry.
- Mouth irritation or mouth sores.
- · Belly pain.
- Hair loss.
- · Headache.
- Back pain.
- · Not able to sleep.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Take in the morning.
- Take this drug at the same time of day.
- Swallow whole. Do not chew, break, or crush.
- Do not take chipped or broken tablets.
- Take as you have been told by your doctor.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal time.

What do I do if I miss a dose?

• Skip the missed dose and go back to your normal time.

• Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store in the original container at room temperature.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 112394 Version 3.0