Ribociclib and Letrozole

This information from Lexicomp® explains what you need to know about this medication, including what it’s used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US
Kisqali Femara Co-Pack

What is this drug used for?

- It is used to treat breast cancer.

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

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- 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 tamoxifen.
- 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 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, diarrhea, or decreased appetite, talk with your doctor. There may be ways to lower these side effects.

- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.

- This drug may cause weak bones. This may happen more often if used for a long time. This may raise the chance of broken bones. Call your doctor right away if you have bone pain.

- Have a bone density test as you have been told by your doctor. Talk with your doctor.
• Have blood work checked as you have been told by the doctor. Talk with the doctor.

• Avoid grapefruit and grapefruit juice.

• Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.

• Some people have had lung problems with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough that is new or worse, or fever.

• This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.

• This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.

• If you may become pregnant, you must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, 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, swallowing, 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, tiredness, decreased appetite, 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, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.

- Signs of low blood sugar like dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating.

- Dizziness or passing out.

- Fast or abnormal heartbeat.

- Swelling in the arms or legs.

- Any unexplained bruising or bleeding.

- Flu-like signs.

**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:

- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.

- Hair loss.

- Feeling tired or weak.
• Headache.
• Back pain.
• Trouble sleeping.
• Mouth irritation or mouth sores.

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.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

**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.
• Be sure you know how to use this drug. Read the instructions that come with this drug. If you have any questions about how to use this drug, talk with the doctor or pharmacist.
• If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal time.
• Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
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.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

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.
- 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.
- Some drugs may have another patient information leaflet. Check with your pharmacist. 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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For more resources, visit www.mskcc.org/pe to search our virtual library.