

PATIENT INFORMATION
KISQALI® (kis kah' lee)
(ribociclib)
tablets

What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

- **Lung problems.** KISQALI may cause severe or life-threatening inflammation of the lungs during treatment that may lead to death. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
 - trouble breathing or shortness of breath
 - cough with or without mucus
 - chest pain
- **Severe skin reactions.** Tell your healthcare provider or get medical help right away if you get severe rash or rash that keeps getting worse, reddened skin, flu-like symptoms, skin pain/burning, blistering of the lips, eyes or mouth, blisters on the skin or skin peeling, with or without fever.
- **Heart rhythm problems (QT prolongation).** KISQALI can cause a heart problem known as QT prolongation. This condition can cause an abnormal heartbeat and may lead to death. Your healthcare provider should check your heart and do blood tests before and during treatment with KISQALI. Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint.
- **Liver problems.** KISQALI can cause serious liver problems. Your healthcare provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your healthcare provider right away if you get any of the following signs and symptoms of liver problems:
 - yellowing of your skin or the whites of your eyes (jaundice)
 - dark or brown (tea-colored) urine
 - feeling very tired
 - loss of appetite
 - pain on the upper right side of your stomach area (abdomen)
 - bleeding or bruising more easily than normal
- **Low white blood cell counts (neutropenia).** Low white blood cell counts are very common during treatment with KISQALI and may result in infections that may be severe. Your healthcare provider should check your white blood cell counts before and during treatment with KISQALI. Tell your healthcare provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.

Your healthcare provider may tell you to decrease your dose, temporarily stop or completely stop taking KISQALI if you develop certain serious side effects during treatment with KISQALI.

See “**What are the possible side effects of KISQALI?**” for more information about side effects.

What is KISQALI?

KISQALI is a prescription medicine used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has gotten worse or has spread to other parts of the body (metastatic), in combination with:

- an aromatase inhibitor as the first endocrine-based therapy; or
- fulvestrant as the first endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

It is not known if KISQALI is safe and effective in children.

Before taking KISQALI, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have ever had a heart attack
- have a slow heartbeat (bradycardia)
- have problems with the amount of potassium, calcium, phosphorus, or magnesium in your blood
- have fever, chills, or any other signs or symptoms of infection
- have liver problems
- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby.
 - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with KISQALI.

- Females who are able to become pregnant and who take KISQALI should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if KISQALI passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take KISQALI?

- Take KISQALI exactly as your healthcare provider tells you.
- Do not change your dose or stop taking KISQALI unless your healthcare provider tells you.
- Take KISQALI each day at about the same time, preferably in the morning.
- Take KISQALI with or without food.
- Swallow KISQALI tablets whole. Do not chew, crush, or split KISQALI tablets before swallowing them.
- Do not take any KISQALI tablets that are broken, cracked, or that look damaged.
- If you miss a dose of KISQALI or vomit after taking a dose of KISQALI, do not take another dose on that day. Take your next dose at your regular time.
- If you take too much KISQALI, call your healthcare provider right away or go to the nearest hospital emergency room.

What should I avoid while taking KISQALI?

Avoid eating grapefruit and drinking grapefruit juice during treatment with KISQALI since these may increase the amount of KISQALI in your blood.

What are the possible side effects of KISQALI?

KISQALI may cause serious side effects, including:

- See "**What is the most important information I should know about KISQALI?**"

The most common side effects of KISQALI include:

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|-------------------------------------|----------------------------------|----------------|-------------------------|
| ● decreased white blood cell counts | ● nausea | ● diarrhea | ● cough |
| ● decreased red blood cell counts | ● increased kidney function test | ● vomiting | ● rash |
| ● abnormal liver function tests | ● tiredness | ● headache | ● back pain |
| ● infections | ● decreased platelet counts | ● constipation | ● low blood sugar level |
| | | ● hair loss | |

KISQALI may cause fertility problems in males, which may affect your ability to father a child. Talk to your healthcare provider if this is a problem for you.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KISQALI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KISQALI?

- Store KISQALI at 68°F to 77°F (20°C to 25°C).
- Keep KISQALI in the original container.

Keep KISQALI and all medicines out of the reach of children.

General information about the safe and effective use of KISQALI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use KISQALI for a condition for which it was not prescribed. Do not give KISQALI to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for more information about KISQALI that is written for health professionals.

What are the ingredients in KISQALI?

Active ingredient: ribociclib

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropylcellulose, magnesium stearate, and microcrystalline cellulose. The film-coating contains iron oxide black, iron oxide red, lecithin (soya), polyvinyl alcohol (partially hydrolyzed), talc, titanium dioxide, and xanthan gum.

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For more information, go to www.KISQALI.com or call 1-844-KISQALI (1-844-547-7254).

This Patient Information has been approved by the U.S. Food and Drug Administration.

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