

PATIENT INFORMATION
KISQALI® FEMARA® CO-PACK (kis kah' lee fe ma' ra koe' pak)
(ribociclib tablets; letrozole tablets)
co-packaged for oral use

What is the most important information I should know about KISQALI FEMARA CO-PACK?

KISQALI FEMARA CO-PACK 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 or 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 FEMARA CO-PACK 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 FEMARA CO-PACK.
 - **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 FEMARA CO-PACK can cause serious liver problems. Your healthcare provider will do blood tests to check your liver before and during treatment with KISQALI FEMARA CO-PACK. 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)	○ loss of appetite
○ dark or brown (tea-colored) urine	○ pain on the upper right side of your stomach area (abdomen)
○ feeling very tired	○ 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 FEMARA CO-PACK 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 FEMARA CO-PACK. 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 FEMARA CO-PACK?**” for more information about side effects.

What is KISQALI FEMARA CO-PACK?

KISQALI FEMARA CO-PACK is a prescription medicine used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer:

- in combination with aromatase inhibitor for stage II and III early breast cancer with a high risk of coming back.
- That has gotten worse or has spread to other parts of the body (advanced or metastatic breast cancer) in combination with an aromatase inhibitor as the first endocrine-based therapy.

KISQALI FEMARA CO-PACK contains 2 different types of medicines:

- The violet tablet contains the medicine KISQALI (ribociclib).
- The yellow tablet contains the medicine FEMARA (letrozole).

It is not known if KISQALI FEMARA CO-PACK is safe and effective in children.

Do not take KISQALI FEMARA CO-PACK if you are allergic to letrozole or any of the ingredients of FEMARA.

See the end of this Patient Information for a list of the ingredients in KISQALI FEMARA CO-PACK.

Before taking KISQALI FEMARA CO-PACK, tell your healthcare provider about all 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 high blood pressure that is not controlled
- have decreased thyroid gland function (hypothyroidism)

- 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
- have kidney problems
- are pregnant, or plan to become pregnant. KISQALI FEMARA CO-PACK 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 FEMARA CO-PACK.
 - Females who are able to become pregnant and who take KISQALI FEMARA CO-PACK should use effective birth control during treatment and for at least 3 weeks after the last dose of KISQALI FEMARA CO-PACK.
 - 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 FEMARA CO-PACK passes into your breast milk. Do not breastfeed during treatment with KISQALI FEMARA CO-PACK and for at least 3 weeks after the last dose of KISQALI FEMARA CO-PACK.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KISQALI FEMARA CO-PACK 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 FEMARA CO-PACK?

- Take KISQALI FEMARA CO-PACK exactly as your healthcare provider tells you.
- Do not change your dose or stop taking KISQALI FEMARA CO-PACK without talking to your healthcare provider.
- KISQALI FEMARA CO-PACK comes in a carton that contains enough KISQALI tablets and FEMARA tablets for 28 days of treatment.
- Take KISQALI FEMARA CO-PACK each day at about the same time, preferably in the morning.
- Take KISQALI FEMARA CO-PACK with food or without food.
- Swallow KISQALI tablets and FEMARA tablets whole. Do not chew, crush or split tablets before swallowing them.
- Do not take any KISQALI tablets and FEMARA tablets that are broken, cracked, or that look damaged.
- If you miss a dose or vomit after taking a dose of KISQALI FEMARA CO-PACK, do not take another dose on that day. Take your next dose at your regular time.

What are the possible side effects of KISQALI FEMARA CO-PACK?

KISQALI FEMARA CO-PACK may cause serious side effects.

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

The most common side effects of KISQALI in people with early breast cancer include:

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| • decreased white blood cell counts | • decreased platelet counts |
| • decreased red blood cell counts | • nausea |
| • increased liver function tests | • headache |
| • infections | • tiredness |
| • increased kidney function test | |

The most common side effects of KISQALI FEMARA CO-PACK in people with advanced or metastatic breast cancer include:

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|-------------------------------------|-----------------------------|----------------|----------------------------------|
| • decreased white blood cell counts | • infections | • headache | • rash |
| • decreased red blood cell counts | • nausea | • hair loss | • increased kidney function test |
| • increased liver function tests | • tiredness | • vomiting | • stomach-area (abdomen) pain |
| | • decreased platelet counts | • back pain | |
| | • diarrhea | • constipation | |
| | | • cough | |

KISQALI FEMARA CO-PACK may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a problem for you.

These are not all of the possible side effects of KISQALI FEMARA CO-PACK.

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 FEMARA CO-PACK?

- Store KISQALI FEMARA CO-PACK at room temperature between 68°F to 77°F (20°C to 25°C).
- Store KISQALI FEMARA CO-PACK in the original blister package in order to protect from moisture.

Keep KISQALI FEMARA CO-PACK and all medicines out of the reach of children.

General information about the safe and effective use of KISQALI FEMARA CO-PACK.

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

What are the ingredients in KISQALI FEMARA CO-PACK?

KISQALI (ribociclib) tablets:

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

FEMARA (letrozole) tablets:

Active ingredient: letrozole

Inactive ingredients: colloidal silicon dioxide, ferric oxide, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, talc, and titanium dioxide

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936

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For more information, go to www.KISQALI.com or call 1-888-669-6682.

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

Revised: September 2025

T2025-60