

For people with HR+, HER2-
stage 2 or 3 early breast
cancer (eBC) with a high
risk of coming back

With KISQALI, I'm

MORE

than just breast cancer



KISQALI + an AI is proven to help reduce the risk of cancer coming back

AI, aromatase inhibitor; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive.

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 in combination with an aromatase inhibitor for stage 2 and stage 3 early breast cancer with a high risk of coming back.

 **KISQALI**[®]
ribociclib 200 mg
tablets



**Please see Important Safety Information throughout, and
full Prescribing Information, including Patient Information.**



Table of contents

<u>Getting started with KISQALI</u>	3
<u>What is KISQALI?</u>	4
<u>Understanding risk in early breast cancer</u>	5
<u>How KISQALI works</u>	6
<u>Results with KISQALI + an AI</u>	7
<u>How to take KISQALI</u>	8
• <u>DOs and DON'Ts of taking KISQALI</u>	10
<u>Monitoring your progress</u>	12
<u>Managing side effects</u>	13
<u>Partnering with your doctor</u>	15
<u>Novartis Patient Support™</u>	16





Getting started with KISQALI

Ready to do more to keep your cancer from coming back—and focus on living today?

Inside, you'll find details on how KISQALI + an AI can **help reduce the risk of cancer returning.**

Let's get started.

[Learn how KISQALI can help prevent cancer from coming back](#)

What is KISQALI? (continued)

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





What is KISQALI?



A **targeted treatment** in **pill** form, known as a cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitor. It is **not chemotherapy**



Approved for **your type of cancer** (HR+, HER2- stage 2 or stage 3 eBC with high risk of cancer returning)



Proven to **help prevent cancer from returning when taken with an AI***

*In clinical trials, invasive disease-free survival, or iDFS, is the term used to describe the time after starting treatment that someone with eBC is still alive, and the cancer has not returned in any part of the body.

[Learn how KISQALI works](#)

IMPORTANT SAFETY INFORMATION

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 health care 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





Hormone therapy alone may not be enough to keep cancer from returning

Up to



1 in 9

people

with stage 2 early breast cancer

Up to



1 in 5

people

with stage 3 early breast cancer

will have their cancer return within 3 years after starting treatment*

It's important that you have an accurate understanding of how likely it is that your cancer may return. There are many factors that can increase risk, such as whether or not you have cancer in your lymph nodes and the size of your tumor. **Talk to your doctor to find out what risk factors you may have.**

*The risk of cancer returning is based on results from clinical trials of people with HR+, HER2- eBC who took an AI.

[See the factors that may cause cancer to return](#)

IMPORTANT SAFETY INFORMATION (continued)

Severe skin reactions. Tell your health care 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.



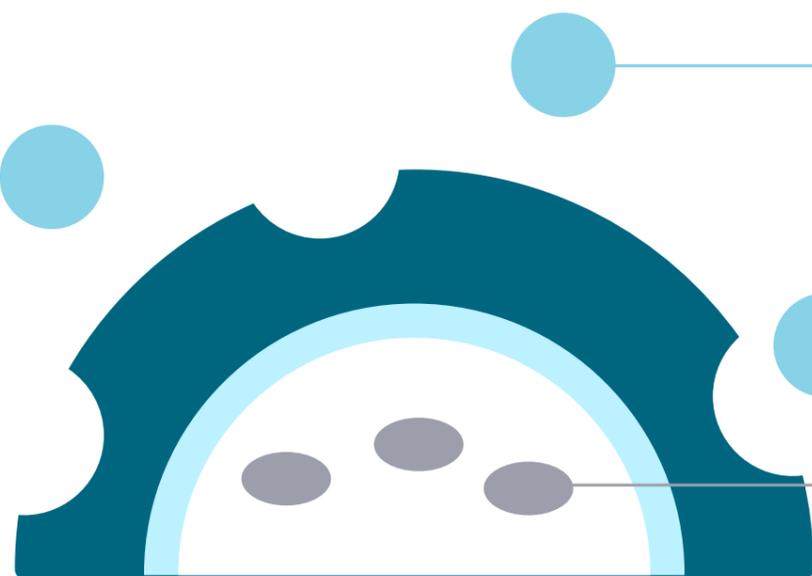
 **KISQALI**[®]
ribociclib 200 mg tablets





KISQALI + an AI work to help stop cancer from coming back

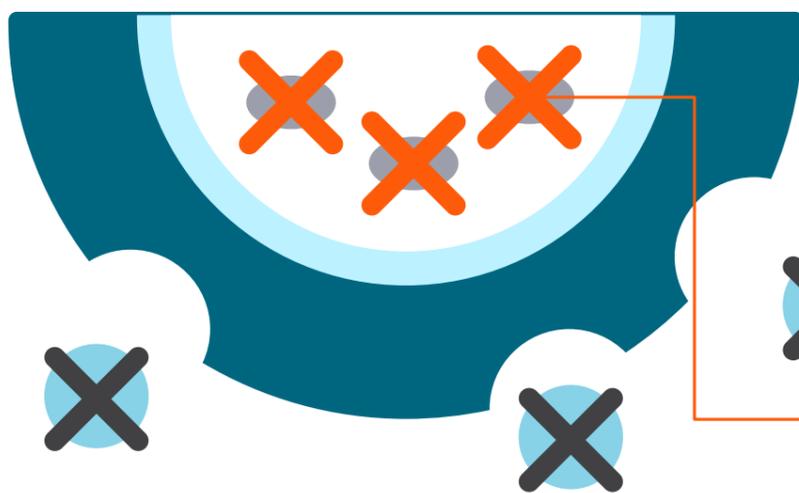
Cancer cell **BEFORE** treatment



In HR+, HER2- eBC, **estrogen** and other hormones trigger proteins called **CDK4** and **CDK6**

These proteins fuel cancer cell growth, which can increase the risk of cancer returning

WITH KISQALI + an AI



Hormone therapy, such as an AI, works by stopping estrogen

KISQALI is designed to directly block CDK4 and CDK6 proteins

CDK 4/6, cyclin-dependent kinases 4 and 6.

IMPORTANT SAFETY INFORMATION (continued)

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 health care provider should check your heart and do blood tests before and during treatment with KISQALI





For patients like you

KISQALI & an AI

is proven to help prevent cancer from coming back*

*For people who have stage 2 or stage 3 HR+, HER2- eBC with a high risk of coming back, including people with and without cancer in their lymph nodes, and people who are pre- or postmenopausal.

Results from the clinical trial were reviewed at 3 and 4 years. The benefit of KISQALI was shown to increase over time.

When the results were reviewed at 3 years

- KISQALI + an AI **cut the risk of cancer returning by 25%** compared to an AI alone
- 91% of people taking KISQALI + an AI were cancer-free, compared with 88% of people taking an AI alone, a difference of 3%

When the results were reviewed at 4 years†

- KISQALI + an AI **cut the risk of cancer returning by 29%** compared to an AI alone
- 89% of people taking KISQALI + an AI were cancer-free, compared with 84% of people taking an AI alone, a difference of 5%

†Results from the 4-year analysis were not designed to detect a false positive or show a difference between treatments.

[See how KISQALI + an AI can help people like you](#)

IMPORTANT SAFETY INFORMATION (continued)

Heart rhythm problems (QT prolongation) (continued)

- Tell your health care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you feel dizzy or faint

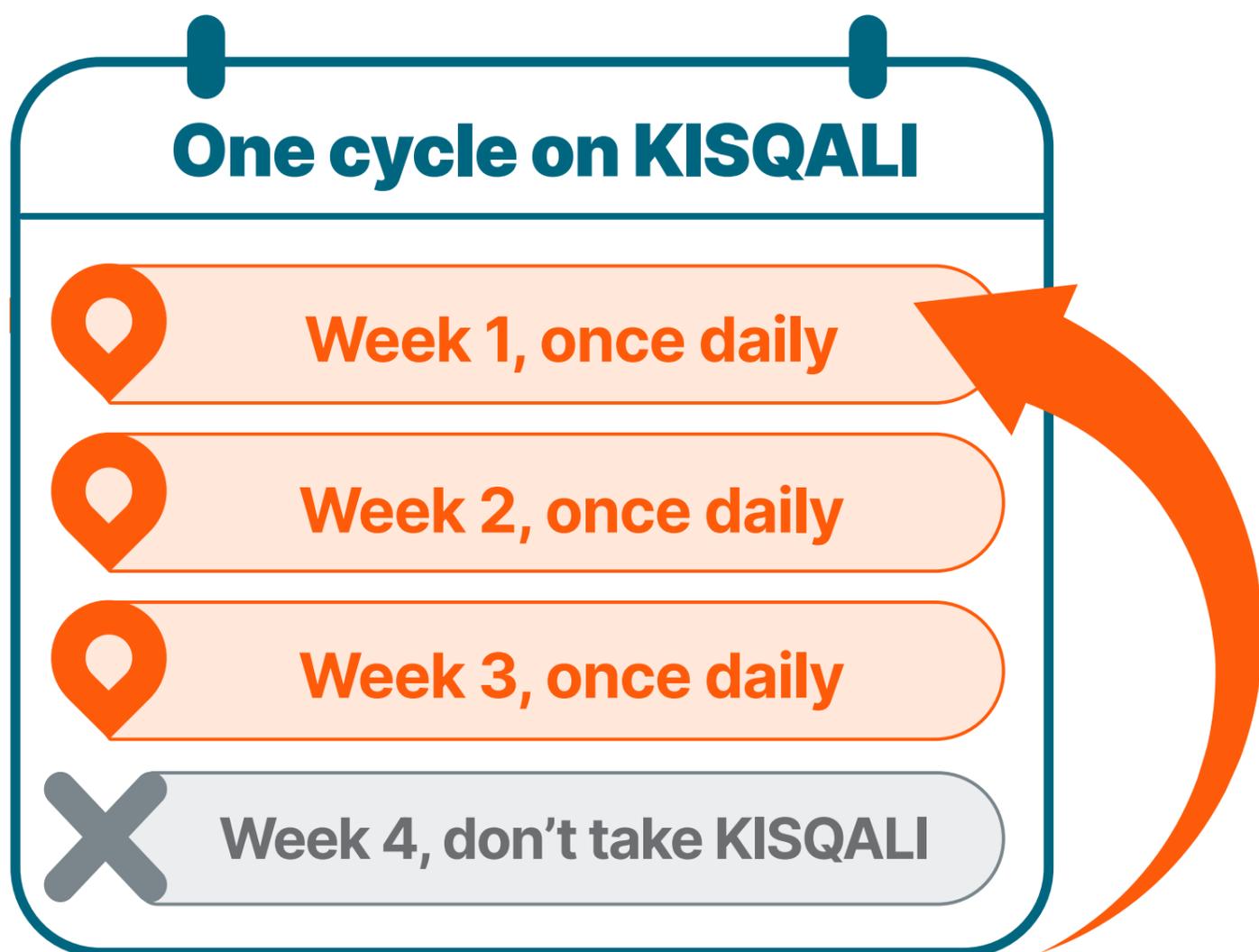




How to take KISQALI

KISQALI is taken

- 400 mg (two 200-mg pills) orally, once a day
- With or without food
- 3 weeks on, followed by 1 week off, for 3 years



One treatment cycle is 28 days.

IMPORTANT SAFETY INFORMATION (continued)

Liver problems. KISQALI can cause serious liver problems. Your health care provider should do blood tests to check your liver before and during treatment with KISQALI. Tell your health care 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





How to take KISQALI (continued)

If your doctor has prescribed KISQALI with



An **aromatase inhibitor (AI)**, you will take this medication orally once a day, every day, for the full 28-day cycle for around 5 years



If you are premenopausal or male, your doctor may also prescribe **goserelin** injections. Your doctor will provide your dosing schedule

**On the following pages:
Learn the DOs and DON'Ts
of taking KISQALI**

IMPORTANT SAFETY INFORMATION (continued)

Liver problems (continued)

- 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 health care provider should check your white blood cell counts before and during treatment with KISQALI. Tell your health care provider right away if you have signs and symptoms of low white blood cell counts or infections, such as fever and chills.





The DOs and DON'Ts of taking KISQALI

Be sure to take KISQALI as your doctor has instructed. Do not change your dose or stop taking KISQALI unless your doctor tells you. Please keep the following in mind:



- ✓ Do try to take KISQALI at the same time every day, preferably in the morning
- ✓ Do swallow KISQALI pills whole. Do not chew, crush, or split them
- ✓ Do store KISQALI in its original packaging at room temperature between 68°F to 77°F (20°C to 25°C) for up to 2 months

IMPORTANT SAFETY INFORMATION (continued)

Low white blood cell counts (neutropenia) (continued)

Your health care 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.

What should I tell my health care provider before taking KISQALI?

Before you take KISQALI, tell your health care provider 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)





The DOs and DON'Ts of taking KISQALI (continued)

Be sure to take KISQALI as your doctor has instructed. Do not change your dose or stop taking KISQALI unless your doctor tells you. Please keep the following in mind:

DON'T

-  Don't take more than 1 dose of KISQALI a day, even if you miss a dose or if you vomit after taking KISQALI. Take your next dose at your regular time
-  Don't take any KISQALI pills that are broken, cracked, or look damaged
-  Don't eat grapefruit or drink grapefruit juice if you are taking KISQALI

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my health care provider before taking KISQALI? (continued)

- 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





Monitoring your progress



As part of your treatment with KISQALI, you may be required to have some routine tests so your doctor can monitor how your body is responding to the medication.

Heart monitoring*

(During first 2 weeks) An electrocardiogram (ECG or EKG). This test is quick and painless and monitors the electrical activity of the heart over time. An ECG can show if there are abnormal conditions and changes in the way electric currents pass through the heart.

Blood monitoring*

(During first 6 months) Blood tests can be used to check your overall health and determine how well your treatment is working. Some specific tests include electrolyte panels, complete blood counts, and liver function tests.

*Your doctor will let you know if additional monitoring is needed.

**When starting a new medicine,
it helps to take note of how you are feeling**

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my health care provider before taking KISQALI? (continued)

- are pregnant, or plan to become pregnant. KISQALI can harm your unborn baby
 - If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI





Managing side effects

In a clinical study, KISQALI was proven to be safe and effective. The most common side effects were generally mild to moderate.



infections



nausea



tiredness



decreased blood cell counts*



headache



increased liver and kidney function tests[†]

These are not all the possible side effects of KISQALI. For additional side effects, see page 17. If you experience any side effects, the most important thing you can do is talk to your doctor.

*Tell your doctor right away if you have signs and symptoms of low blood cell counts or infections, such as fever and chills.

[†]Tell your doctor right away if you get any of these 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.

Get tips on managing side effects

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my health care provider before taking KISQALI? (continued)

- 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





Managing side effects (continued)

Most common side effects of KISQALI can be managed with dose reductions. Studies show that even with a reduced dose, the benefit of KISQALI + an AI is maintained*

*Data from a clinical trial were further analyzed to assess the results when a dose reduction was required. This analysis was not preplanned and results should be interpreted with caution. Take KISQALI exactly as your doctor tells you to and do not stop taking KISQALI or change the dose without talking to your doctor. The recommended dose of KISQALI (in combination with an aromatase inhibitor) for eBC is 400 mg orally once a day for 3 weeks on, followed by 1 week off.

[Get tips on managing side effects](#)

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my health care provider before taking KISQALI? (continued)

- Talk to your health care 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 health care provider right away





Partnering with your doctor



Understanding your cancer diagnosis and treatment plan can help you feel more in control. **Your doctor and care team** are there to make sure you have the best experience possible with KISQALI. Now's the time to ask questions and talk about your concerns.

Taking an active role in your care can help set you up for success

[See how KISQALI can help you](#)

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my health care provider before taking KISQALI? (continued)

- 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





Patient portrayal.

Novartis Patient Support™

**Personalized support that
can help you start, stay, and save
on treatment**

What does personalized support mean? It means that at every step you'll get help from a go-to team member with **financial, insurance, and ongoing support.**

[Sign up for support](#)

or call 1-866-433-8000



 **KISQALI**®
ribociclib 200 mg
tablets





IMPORTANT SAFETY INFORMATION (continued)

Tell your health care 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 health care provider or pharmacist when you get a new medicine.

What should I avoid while taking KISQALI?

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

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

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





IMPORTANT SAFETY INFORMATION (continued)

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

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

These are not all the possible side effects of KISQALI. For more information, ask your health care provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Important Safety Information throughout, and full Prescribing Information, including Patient Information.

