THE REAL DEAL
ABOUT
GETTING STARTED

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
INDICATIONS

KISQALI® (ribociclib) is a prescription medicine used in combination with:

• an aromatase inhibitor to treat pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic), as the first endocrine-based therapy; or
• fulvestrant to treat postmenopausal women with HR-positive, HER2-negative metastatic breast cancer as the first endocrine-based therapy or with disease progression following endocrine therapy

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

IMPORTANT SAFETY INFORMATION

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

KISQALI may cause serious side effects, including:

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. 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.

Welcome to KISQALI

You’ve probably had conversations with your doctor about what it means to have advanced or metastatic breast cancer—when breast cancer has spread to other parts of the body.

Learning that you have metastatic breast cancer is life-changing. You may feel shocked and overwhelmed. As you process your diagnosis, it’s important to remember that you didn’t do anything wrong. This is not your fault.

Treatment will now be part of your daily routine. That’s why your doctor prescribed KISQALI along with hormone therapy (eg, letrozole or anastrozole) or fulvestrant for your specific type of advanced or metastatic breast cancer. KISQALI is the first and only therapy of its kind indicated in combination with hormone therapy for premenopausal women with HR-, HER2- metastatic breast cancer. KISQALI is also indicated for postmenopausal women in combination with fulvestrant or hormone therapy.

KISQALI is a breakthrough therapy that received approval from the US Food and Drug Administration (FDA) based on the need for more treatments for a wide range of women living with metastatic breast cancer. Explore this booklet to find information about what you can expect from KISQALI, including treatment results from clinical studies, and possible side effects.

Sincerely,

Your KISQALI Team

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
UNDERSTANDING THE DISEASE

“My diagnosis changed my life in an instant. But it will never change who I am.”

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
About Metastatic Breast Cancer

There are multiple stages of breast cancer, ranging from 0–4. When breast cancer progresses to stage 4, it's called metastatic breast cancer (mBC) or advanced breast cancer. The word "metastatic" means that the breast cancer cells have spread beyond the breast to other parts of the body.

Types of Metastatic Breast Cancer

Each type of metastatic breast cancer is determined by whether or not cancer cells have certain proteins: hormone receptors (HRs) and human epidermal growth factor receptor 2 (HER2). A plus sign means your cancer has the protein, and a minus sign means that it has either a small amount of the protein or none at all.

- **HR+/HER2-**
- **HR-/HER2-**
- **HR+/HER2+**
- **HR-/HER2+**

**HR+, HER2- is the most common type of metastatic breast cancer**

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.

Facts & Figures About Metastatic Breast Cancer

- An estimated 155,000 US women are living with metastatic breast cancer
- It is estimated that, as of January 2017, more than 20,000 women with mBC in the United States were younger than 50.
- The frequency of metastatic disease in women under 40 has increased over the last 30 years
- 20% to 30% of people with an early-stage diagnosis eventually develop stage 4 metastatic breast cancer
- Nearly 80% of younger women diagnosed discover their breast cancer themselves
- There is no cure for metastatic breast cancer, but it can be treated
- Treatment is lifelong, and focuses on slowing the growth and spread of tumors

**IMPORTANT SAFETY INFORMATION (continued)**

Liver problems (hepatobiliary toxicity). KISQALI® (ribociclib) 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:
ABOUT KISQALI

“With metastatic breast cancer, I can't control my outcome, but I can control my outlook.”

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
Results for premenopausal women taking KISQALI + letrozole or anastrozole + goserelin

**IMPORTANT SAFETY INFORMATION (continued)**

- yellowing of your skin or the whites of your eyes (jaundice)
- feeling very tired
- pain on the right side of your stomach area (abdomen)
- dark or brown (tea-colored) urine
- loss of appetite
- bleeding or bruising more easily than normal

Live longer without disease progression

In a clinical trial dedicated exclusively to younger women, 495 patients were treated with KISQALI + hormone therapy (eg, letrozole or anastrozole) or hormone therapy alone. KISQALI + hormone therapy helped premenopausal women live longer without disease progression.

2+ years of progression-free survival

<table>
<thead>
<tr>
<th>Median time women lived without disease progression from the start of treatment</th>
<th>KISQALI + letrozole or anastrozole + goserelin</th>
<th>letrozole or anastrozole + goserelin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trials are still ongoing to see if patients live longer with treatment</td>
<td>27.5</td>
<td>13.8</td>
</tr>
</tbody>
</table>

Trials are still ongoing to see if patients live longer with treatment.

Proven to shrink tumors

KISQALI + letrozole or anastrozole + goserelin worked together to shrink tumors in women who had measurable tumors.

**MORE THAN HALF**

51% of women taking KISQALI + letrozole or anastrozole + goserelin had tumors that shrank or disappeared vs 34% of women taking letrozole or anastrozole + goserelin.

*48% of women taking KISQALI + letrozole or anastrozole + goserelin saw their tumors shrink in size vs 34% of those taking letrozole or anastrozole + goserelin. And 3% of women taking KISQALI + letrozole or anastrozole + goserelin had their tumors completely disappear vs 3% of those taking letrozole or anastrozole + goserelin.

*Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.*

**About MBC**

**About KISQALI**

**How KISQALI Works**

**Taking KISQALI**

**Side Effects**

**Support Services**

**Real Advice**

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9
Results for postmenopausal women taking KISQALI + letrozole

IMPORTANT SAFETY INFORMATION (continued)

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking KISQALI® (ribociclib) 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. 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.

Live longer without disease progression

KISQALI works in combination with a hormone therapy to delay the progression of metastatic breast cancer in postmenopausal women. In a clinical trial of 668 women, KISQALI + letrozole reduced the risk of disease progression by 44% vs letrozole alone. At the time of this analysis, more than half of women taking KISQALI + letrozole remained alive and progression free.

2+ years of progression-free survival

WITH KISQALI + LETROZOLE

There were fewer women who progressed with KISQALI + letrozole compared to those taking letrozole alone. Median progression-free survival for patients taking KISQALI + letrozole was 25.3 months vs 16.0 months for those taking letrozole alone.

Proven to shrink tumors

KISQALI and letrozole worked together to shrink tumors in women who had measurable tumors.

53% of women taking KISQALI + letrozole had tumors that shrunk or disappeared vs 37% of women taking letrozole alone.

This check-in was not designed to measure tumor size reduction. Based on the design of the trial, this result may not have been caused by the treatment.

More than half saw tumor shrinkage at the first trial check-in (observed 8 weeks after starting treatment).

3 OUT OF 4 WOMEN saw tumor shrinkage at the first trial check-in (observed 8 weeks after starting treatment).

50% of women taking KISQALI + letrozole saw their tumors shrink in size vs 35% of those taking letrozole alone. And 3% of women taking KISQALI + letrozole had their tumors completely disappear vs 2% of those taking letrozole alone.

MORE THAN HALF

53% of women taking KISQALI + letrozole had tumors that shrunk or disappeared vs 37% of women taking letrozole alone.

3 OUT OF 4 WOMEN saw tumor shrinkage at the first trial check-in (observed 8 weeks after starting treatment).

About MBC

About KISQALI

How KISQALI Works

Taking KISQALI

Side Effects

Support Services

Real Advice

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
Results for postmenopausal women taking KISQALI + fulvestrant

IMPORTANT SAFETY INFORMATION (continued)

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

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)
- 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 any other medical conditions

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.

Live longer without disease progression

KISQALI is used along with the medicine fulvestrant in postmenopausal women who are either newly diagnosed with HR+, HER2- metastatic breast cancer, or who have already received hormone therapy.

20.5 months of progression-free survival

Proven to shrink tumors

In a clinical trial, 726 patients were treated with either KISQALI + fulvestrant or fulvestrant alone. KISQALI + fulvestrant worked together to shrink tumors in women who had measurable tumors.

41% of women taking KISQALI + fulvestrant had tumors that shrunk or disappeared vs 29% of women taking fulvestrant alone. And 2% of women taking KISQALI + fulvestrant had their tumors completely disappear vs 0% of those taking fulvestrant alone.

41% of women taking KISQALI + fulvestrant had tumors that shrunk or disappeared vs 29% of women taking fulvestrant alone. *39% of women taking KISQALI + fulvestrant saw their tumors shrink in size vs 29% of those taking fulvestrant alone. And 2% of women taking KISQALI + fulvestrant had their tumors completely disappear vs 0% of those taking fulvestrant alone.

Median time women lived without disease progression from the start of treatment

- KISQALI + fulvestrant: 20.5 months
- Fulvestrant alone: 12.8 months

Trials are still ongoing to see if patients live longer with treatment.
“Having this illness is scary. But I’m not afraid to ask the tough questions.”

HOW KISQALI WORKS

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
IMPORTANT SAFETY INFORMATION (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.
  - 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.

KISQALI® (ribociclib) is a targeted treatment, meaning it blocks, or interferes with, substances that play a role in cancer cell growth. Targeted therapies affect cancer cells, but can also affect healthy cells. To understand how KISQALI works with hormone therapy or fulvestrant, it’s important to also understand the role that hormones/hormone receptors play in causing your type of cancer cells to grow and divide.

KISQALI works in combination with a hormone therapy (eg, letrozole or anastrozole) or fulvestrant

KISQALI blocks CDK4/6 activity, helping to prevent cell division

Treatment with KISQALI in combination with a hormone therapy or fulvestrant

Hormone therapy or fulvestrant limits estrogen levels

Hormones, like estrogen, or hormone receptors

KISQALI

CDK4/6 proteins

activate CDK4/6 proteins

causing cell division

HR+, HER2-metastatic breast cancer growth

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.

KISQALI works with either a hormone therapy or fulvestrant to help delay disease progression

Hormones, like estrogen, or hormone receptors

KISQALI

CDK4/6 proteins

activates CDK4/6 proteins

causing cell division

HR+, HER2-metastatic breast cancer growth

About MBC

About KISQALI

How KISQALI Works

Side Effects

Support Services

Real Advice

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Non-Tab Page: 6”

Tab Page or Cover: 18”

Tab Page or Cover: 6”
"Metastatic breast cancer is as serious as it gets. So I got serious about my treatment options."

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
How to take KISQALI

KISQALI® (ribociclib) is a once-daily oral tablet prescribed with an oral hormone therapy (eg, letrozole or anastrozole) or with fulvestrant, an injection administered by your health care provider. It is important to follow your doctor’s directions on how to take KISQALI.

IMPORTANT SAFETY INFORMATION (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.
° 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.

KISQALI + hormone therapy

Recommended Dosing

For the first 3 weeks in a cycle, you’ll take your 3 KISQALI pills in combination with a hormone therapy. The fourth week, you won’t take any KISQALI pills—you’ll only take your hormone therapy. After the fourth week, your doctor may have you start the same cycle over again, or may adjust your dose if needed.

- The recommended starting dose of KISQALI is 600 mg (three 200-mg tablets), taken once daily
- Ask your doctor about the recommended dose of your hormone therapy

<table>
<thead>
<tr>
<th></th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>KISQALI</td>
<td>✔</td>
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<td>✔</td>
<td>☒</td>
</tr>
<tr>
<td>600 mg (three 200-mg tablets) once daily for 3 weeks, followed by 1 week without taking KISQALI</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Hormone therapy (eg, letrozole or anastrozole)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Follow your doctor’s recommended dosing schedule</td>
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</tr>
</tbody>
</table>

Treatment is taken once daily during that week of the cycle. ☒ Treatment is not taken during that week of the cycle.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
KISQALI + fulvestrant

Recommended Dosing

KISQALI® (ribociclib) is taken orally on a 4-week dosing cycle. For the first 3 weeks in a cycle, you’ll take your 3 KISQALI pills once daily. On the fourth week, you won’t take any KISQALI pills. Your doctor may adjust your dose if needed. Fulvestrant is an injection administered by your health care provider, taken in combination with KISQALI.

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>KISQALI</td>
<td>600 mg (three 200-mg tablets) once daily for 3 weeks, followed by 1 week without taking KISQALI</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

**First Month (3 doses)**

<table>
<thead>
<tr>
<th>Weekend</th>
<th>Day 1</th>
<th>Day 15</th>
<th>Day 29</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULVESTRANT</td>
<td>500-mg dose on days 1, 15, and 29 during the first month of treatment, and 500-mg dose once monthly thereafter</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.

**IMPORTANT SAFETY INFORMATION (continued)**

Tell your health care provider about all of 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.
Dosing Instructions

- Take KISQALI® (ribociclib) each day at about the same time, preferably in the morning.
- Take the recommended dose of KISQALI. Do not take more than prescribed.
- Swallow KISQALI tablets whole, with or without food.
- Do not chew, crush, or split KISQALI tablets.
- If you take too much KISQALI, call your doctor right away or go to the nearest hospital emergency room.
- Avoid grapefruit or grapefruit juice.

IMPORTANT SAFETY INFORMATION (continued)

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.
"Metastatic breast cancer wasn't in my plans. But I plan on taking it head on."

STRAIGHT TALK ABOUT SIDE EFFECTS

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
Side effects

It's only natural to have concerns about side effects when starting a new treatment. KISQALI® (ribociclib) may cause side effects that you are not familiar with. 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. Contact your doctor if you experience any of the following side effects:

Serious side effects

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. 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
- feeling very tired
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Liver problems (hepatobiliary toxicity). 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:

- jaundice
- dark or brown (tea-colored) urine
- feeling very tired
- loss of appetite
- pain on the 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 when taking 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.

If you have any side effects, your doctor may direct you to stop taking KISQALI for a while, use a lower dose, or stop taking it permanently. Always follow your doctor’s instructions.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of KISQALI include:

- neutropenia
- vomiting
- infections
- headache
- diarrhea
- rash
- nausea
- hair loss
- fatigue
- constipation
- leukopenia
- cough

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
The most common side effects of KISQALI include:
- neutropenia
- nausea
- infections
- fatigue
- diarrhea
- leukopenia

Monitoring requirements
As part of your treatment with KISQALI, you may be required to have some routine tests so your health care provider can monitor how your body reacts to the medication.

IMPORTANT SAFETY INFORMATION (continued)
KISQALI may cause fertility problems if you are male and take KISQALI. This 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.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
Tips your doctor may suggest for managing some common side effects

Here’s a list of suggestions that your doctor may offer to help you manage some of the side effects of KISQALI® (ribociclib). Always talk to your doctor before making any changes to your diet or exercise routine.

General tips for staying healthy while on KISQALI

• Wash your hands often
• Stay hydrated
• Avoid anyone who is sick
• Avoid raw food and undercooked meats
• Avoid hot tubs, ponds, rivers, and lakes

Diarrhea

• Drink plenty of water, sports drinks, juice, or clear broth
• Avoid spicy and/or greasy foods, alcohol, coffee, tea, and soda with caffeine
• Avoid milk and dairy products
• Eat food high in protein, such as beef, chicken, turkey, eggs, fish, and cheese
• Eat small amounts of soft, bland food. Try the BRAT Diet: Bananas, Rice, Applesauce, and Toast

IMPORTANT SAFETY INFORMATION (continued)

These are not all of 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 accompanying full Prescribing Information including Patient Information.

Nausea and vomiting

• Eat small meals throughout the day
• Avoid eating when you feel nauseous
• Take small sips of water throughout the day
• Try meditation or other relaxation techniques

Tiredness

• Get plenty of rest
• Stay hydrated
• Try getting small amounts of physical activity
• Avoid drinking alcohol and caffeinated beverages at night

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
SUPPORT SERVICES

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.

“A lot is uncertain when you have this condition. It’s good to know that I’m not alone.”
Savings and Support Made Simple

We understand that starting a new treatment can feel overwhelming, and that you may have a lot of questions. That’s why we created KISQALI Care, a comprehensive patient support program that provides you with a dedicated navigator who can help you get the most out of the available patient support.

KISQALI Care Patient Navigator

The KISQALI Care Patient Navigator is available to help you throughout your treatment with KISQALI® (ribociclib). While enrolled in the program, you will receive a series of phone calls from a specially trained navigator to support and guide you through various aspects of starting on KISQALI.

Program features include:

- **Personal phone calls** that fit into your schedule
- **Educational information** about your medication
- **Financial assistance information**
- Support in **understanding insurance coverage**
- Help with **identifying/determining pharmacies** covered by your plan

This program does not provide medical advice or replace your regular interactions with your health care team.

For more information, call 1-800-282-7630.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
**1 FREE Treatment Cycle of KISQALI and/or FEMARA**

Patients are eligible to receive a 1-treatment cycle supply of any one of the following at no cost.*

a. KISQALI® (ribociclib)

b. FEMARA® (letrozole)

c. letrozole

d. KISQALI + FEMARA

e. KISQALI + letrozole

Call 1-800-282-7630 or visit [www.FreeTreatmentVoucher.com](http://www.FreeTreatmentVoucher.com) to receive your free treatment voucher.

*No purchase required of KISQALI or FEMARA (including generic letrozole). This offer is available for patients with a valid prescription for KISQALI and/or FEMARA (including generic letrozole), including for patients who have not been prescribed KISQALI or another Novartis product.

**5 KISQALI 5-Treatment Cycle Access Program**

Patients with commercial insurance who are still waiting for their coverage to take effect for KISQALI may be eligible for an additional supply of KISQALI that could continue for up to 5 treatment cycles.

For more information, talk to your doctor or call 1-800-282-7630 to speak with a KISQALI Care Patient Navigator.

*Limitations apply. Eligible patients must have commercial insurance, a completed Service Request Form, and be experiencing a delay in obtaining coverage for KISQALI. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, Tricare, or any other federal or state program. No purchase necessary. Participation is not a guarantee of insurance coverage. Once coverage is approved, patients will no longer be eligible. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this Program without notice.

**KISQALI and/or FEMARA $0 Co-Pay**

You may be eligible for immediate co-pay savings on your next prescription of KISQALI and/or FEMARA (including generic letrozole).

- Eligible patients with private insurance may pay $0 per month

- Novartis will pay the remaining co-pay, up to $15,000 per calendar year, per product

*Limitations apply. This offer is only available to patients with private insurance. Use of this offer for FEMARA (or generic letrozole) does not require a KISQALI prescription. Offer is NOT valid for purchases of FEMARA only by California or Massachusetts residents. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit [www.CoPay.NovartisOncology.com](http://www.CoPay.NovartisOncology.com) or call 1-877-577-7756.


Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
“Living with this disease can feel isolating. That’s why I surrounded myself with people I trust.”
REAL TALK from real women living with metastatic breast cancer

Here are some words of encouragement from other women to help you stay motivated to be your own best advocate.

"Keep in mind that this is not your fault."
"Create a strong partnership with your doctor."
"Be an active participant when it comes to your treatment."
"Keep learning, so you can make informed decisions."
"Ask for help when you need it—you are not alone in this."
"Don’t put your life on hold—keep living as fully as possible."
"Remain hopeful—don’t let metastatic breast cancer define you."

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44–47.
What is the most important information I should know about KISQALI?

KISQALI may cause serious side effects, including:

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. 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.

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

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking 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.

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
- feeling very tired
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

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
- feeling very tired
- loss of appetite
- pain on the 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 when taking 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.

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)
- 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 any other medical conditions
- 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.
  * 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.

KISQALI® (ribociclib)

KISQALI is a prescription medicine used in combination with:

- an aromatase inhibitor to treat pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic), as the first endocrine-based therapy; or
- fulvestrant to treat postmenopausal women with HR-positive, HER2-negative metastatic breast cancer as the first endocrine-based therapy or with disease progression following endocrine therapy.

It is not known if KISQALI is safe and effective in children.
Summary of Important Information (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.
• are breastfeeding or plan to breastfeed. It is not known if KISQALI® (ribociclib) passes into your breast milk. Do not breastfeed during treatment with KISQALI and for at least 3 weeks after the last dose of KISQALI.

**What other medications might interact with KISQALI?**

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements (especially St. John’s wort). 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.

**What laboratory tests do I need if I am prescribed KISQALI?**

Your doctor should check your heart rhythm, liver, and blood before you start KISQALI and periodically during your treatment with KISQALI. Your doctor may eventually stop checking some of these tests. If you are able to become pregnant, your health care provider should do a pregnancy test before you start treatment with KISQALI.

The most common side effects of KISQALI include:

• neutropenia
• nausea
• infections
• fatigue
• diarrhea
• leukopenia

KISQALI may cause fertility problems if you are male and take KISQALI. This 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 of 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**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 it to other people, even if they have the same symptoms you have. It may harm them. You can ask your health care provider or pharmacist for more information about KISQALI.

For more information, go to [www.kisqali.com](http://www.kisqali.com) or call 1-844-KIS-QALI (1-844-547-7254).

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Visit [www.KISQALI.com](http://www.KISQALI.com) to learn more—and explore resources that can support you throughout your treatment journey.