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 (e.g., letrozole or anastrozole) or fulvestrant for your specific type of advanced or metastatic breast cancer: hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, or HR+, HER2-.

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.
"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.
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- is the most common type of metastatic breast cancer.
“With metastatic breast cancer, I can't control my outcome, but I can control my outlook.”
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

Results for premenopausal women taking KISQALI + letrozole or anastrozole + goserelin

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

KISQALI + letrozole or anastrozole + goserelin

<table>
<thead>
<tr>
<th>Survival Time</th>
<th>Median Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 months</td>
<td>13.8</td>
</tr>
<tr>
<td>15 months</td>
<td>27.5</td>
</tr>
</tbody>
</table>

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

51% of women taking KISQALI + letrozole or anastrozole + goserelin had tumors that shrank or disappeared vs 48% of women 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.

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.

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

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

IMPORTANT SAFETY INFORMATION (continued)

Results for postmenopausal women taking KISQALI + letrozole

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

<table>
<thead>
<tr>
<th>Median time women lived without disease progression from the start of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>KISQALI + letrozole</td>
</tr>
<tr>
<td>Letrozole alone</td>
</tr>
</tbody>
</table>

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

MORE THAN HALF
53% of women taking KISQALI + letrozole had tumors that shrank or disappeared vs 37% of women taking letrozole alone.

3 OUT OF 4 WOMEN
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.

As measured during a trial follow-up
Trials are still ongoing to see if patients live longer with treatment.

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.

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.*

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

0 months 15 months 30 months

fulvestrant alone 12.8
KISQALI + fulvestrant 20.5

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

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.*

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

0 months 15 months 30 months

fulvestrant alone 12.8
KISQALI + fulvestrant 20.5

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

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.*

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.*
"Having this illness is scary. But I’m not afraid to ask the tough questions."
KISQALI works in combination with either a hormone therapy or fulvestrant to help delay disease progression.

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.

**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.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 44-47.
“Metastatic breast cancer is as serious as it gets. So I got serious about my treatment options.”
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.
- If you 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>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️ KISQALI 600 mg (three 200-mg tablets) once daily for 3 weeks, followed by 1 week without taking KISQALI</td>
<td>✔️ ✔️ ✔️ ✔️ (Treatment is taken once daily during that week of the cycle.)</td>
<td>✔️ ✔️ ✔️ ✔️ (Treatment is taken once daily during that week of the cycle.)</td>
<td>✗ ✔️ ✔️ ✔️ (Treatment is not taken during that week of the cycle.)</td>
</tr>
</tbody>
</table>

Hormone therapy (eg, letrozole or anastrozole)

Follow your doctor’s recommended dosing schedule

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

<table>
<thead>
<tr>
<th>First Month (3 doses)</th>
<th>Following Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULVESTRANT 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>
</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.

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.

Do not chew, crush, or split KISQALI tablets.

Take the recommended dose of KISQALI. Do not take more than prescribed.

If you take too much KISQALI, call your doctor right away or go to the nearest hospital emergency room.

Swallow KISQALI tablets whole, with or without food.

Avoid grapefruit or grapefruit juice.

Dose Adjustments

KISQALI offers dosing flexibility to help your doctor find the dose of KISQALI that’s right for you.

Your doctor may lower your dose, interrupt your dose, or stop treatment with KISQALI to help you manage side effects.

KISQALI dosing can easily be adjusted by your doctor to fit your needs.

You won’t need to obtain a new prescription if your doctor decides to lower your dose.

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.

The number of 200-mg tablets may be reduced from 3 tablets to 2 tablets to 1 tablet, according to your doctor’s instructions.
Metastatic breast cancer wasn’t in my plans. But I plan on taking it head on.”
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.

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:

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 notice 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 notice any of the following 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.

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.
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.

KISQALI Care, our comprehensive patient support program, can provide you with a dedicated person who will be there to help schedule your required monitoring tests, including electrocardiograms (ECGs) and bloodwork, in the comfort of your own home (for eligible patients). *

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.

*Limitations apply. KISQALI Care @ Home Monitoring is not available to patients with Medicare, Medicaid, or any other federal or state program, or residents of Michigan or Rhode Island. Novartis reserves the right to terminate or modify this program at any time.

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

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

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.
“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
• Assistance with scheduling monitoring tests for eligible patients using our KISQALI Care @ Home Monitoring program*

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.

*Limitations apply. KISQALI Care @ Home Monitoring is not available to patients with Medicare, Medicaid, or any other federal or state program, or residents of Michigan or Rhode Island. Novartis reserves the right to terminate or modify this program at any time.
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

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.

Call 1-800-282-7630 or visit www.FreeTreatmentVoucher.com to receive your free treatment voucher.

You may be eligible for immediate co-pay savings on your next KISQALI and/or FEMARA (including generic letrozole) prescriptions:
• Commercially insured patients pay $0 per month.
• Novartis will pay the remaining co-pay, up to $15,000 per calendar year per product.

Limitations apply. Eligible patients must have commercial insurance. Offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit www.CoPay.NovartisOncology.com or call 1-877-577-7756.

About KISQALI
How KISQALI Works
Taking KISQALI
Side Effects
Support Services
Real Advice

KISQALI Care is brought to you by Novartis Patient Assistance Now Oncology.

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.
Summary of Important Information

What is 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.

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.

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

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.

Tell 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.

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
  • vomiting
  • hair loss
  • headache
  • constipation
  • rash
  • cough

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.

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 or call 1-844-KIS-QALI (1-844-547-7254).
Visit www.KISQALI.com to learn more—and explore resources that can support you throughout your treatment journey.