



My HR-positive, HER2-negative early breast cancer treatment with ^{Pr}KISQALI[®]

EVERYTHING I NEED TO KNOW ABOUT MY TREATMENT WITH ^{Pr}KISQALI[®] ribociclib

KISQALI[®] is used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer. This means the cancer is localized to the breast or could have spread to the lymph nodes in the region of the breast, with no detectable spread to other parts of the body, has been surgically removed, and has certain characteristics that increase the risk of the cancer returning. KISQALI[®] is used in combination with an aromatase inhibitor, which is used as hormonal anticancer therapy to prevent the cancer from coming back after surgery.

 **NOVARTIS**

scan to visit
Kisqali.ca



About this brochure

In this brochure you will find



Information about your therapy, potential side effects and how to manage them

Please refer to the links in section “Additional information and contacts”, which will take you to the websites or resources with additional information. We encourage you to check out the website or reach out to the suggested contacts for additional information. It can also be helpful for you to participate in patient support programs. You will find more detailed information on this on page 19 of this brochure.

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1. Understanding your treatment with KISQALI®

1.1 What is KISQALI® and why has it been prescribed to me?

KISQALI® is used to treat adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative early breast cancer. This means the cancer is localized to the breast or could have spread to the lymph nodes in the region of the breast, with no detectable spread to other parts of the body, has been surgically removed, and has certain characteristics that increase the risk of the cancer returning.

KISQALI® is used in combination with an aromatase inhibitor, which is used as hormonal anticancer therapy to prevent the cancer from coming back after surgery.

1.2 How does this medication work?

KISQALI® belongs to a family of medications called kinase inhibitors. These medications work by stopping cancer cells from dividing and growing. KISQALI® is used together with an aromatase inhibitor. When given together, KISQALI® may slow down the growth and spread of breast cancer cells.

2. How do I take KISQALI®?

2.1 How do I take this medication?

KISQALI® will always be taken in combination with a hormonal therapy. Hormonal therapy is given through the administration of drugs known as aromatase inhibitors (for example, Letrozole or Anastrozole). Both forms of therapy are taken as tablets.



KISQALI® + aromatase inhibitor

- The recommended dose is 400 mg orally (2 tablets of 200 mg) once daily for 21 consecutive days, followed by 7 days off-treatment

Dose reduction

If you have certain side effects, your healthcare professional may ask you to take less medicine, to skip a dose, or to stop treatment.



Treatment cycles

KISQALI® is taken together with a hormonal therapy (aromatase inhibitor) in a 28-day cycle. Make sure to speak with your doctor about the dosing and administration of the aromatase inhibitor before starting treatment.

28-Day-Cycles	Week 1	Week 2	Week 3	Week 4
KISQALI® 200 mg x 2 (= 400 mg) once daily Taken for 3 weeks, followed by 1-week break	✔	✔	✔	✘

- ✔ Take the medication 1x daily for the corresponding week in the cycle.
- ✘ Do not take the medication during the corresponding week in the cycle.



Aromatase inhibitor
 Taken as prescribed



Continue taking KISQALI® for as long as your healthcare professional tells you to. This is a long-term treatment, possibly lasting for months or years.

**Always follow
 your healthcare
 team's directions
 on how to take
 KISQALI®**

Please note the following information on how to take KISQALI®



Take once daily, preferably in the morning.



Swallow the tablets whole with water. Do not chew, crush, or cut up the tablets before swallowing them.



Take with or without food.



You should not eat grapefruit or drink grapefruit juice while you are taking KISQALI®. They may increase the amount of KISQALI® in your blood and affect how KISQALI® works.



Certain medications and supplements (e.g., St. John's wort, antibiotics, antifungal medications, antiviral medications for diseases such as HIV and hepatitis, medications for heart disease, high blood pressure or epilepsy) may affect the efficacy of your KISQALI®. For this reason, always speak to your healthcare team before you take any other medications or supplements.



Tips to help remember your daily dose:

Be sure to make a note every day once you have taken your KISQALI® tablets.



Take the tablets as part of a daily activity, such as at breakfast, after brushing your teeth, or after doing your morning stretches



Set an alarm on your smartphone or alarm clock



Ask your friends and family to remind you to take it

2.2 Managing my medication

Managing your medication effectively means being prepared for situations that may occur and knowing how best to handle them. Use these instructions if any of the following occur:

If you miss a dose:

- The tablets for that missed dose should be discarded
- Take your next dose at your regular time the following day until your 21-day treatment is complete
- Do not replace a missed dose on subsequent days to avoid affecting the 7 days off treatment

If you vomited after taking your tablets:

- Do not take any additional tablets

If you accidentally took too many tablets:

- Contact your healthcare professional, hospital emergency department, regional poison control center or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms



Important

Do not change the dose or dosing schedule of KISQALI® in any way without consulting your healthcare professional

3. Side effects and support



3.1 What are the possible side effects of KISQALI®?

The following serious side effects have been seen in people taking KISQALI®:

- Heart problems: chest pain or discomfort, heart palpitations, fast or slow heartbeat, dizziness, lightheadedness, fainting, sudden death
- Liver problems: itching, yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite
- Low levels of white blood cells: fever, sore throat, mouth ulcers or other signs of infections

For information on further possible side effects, please read the package inserts of your medications and ask your healthcare team

Talk to your doctor if you experience any of these side effects

Very common	Common
<ul style="list-style-type: none"> • Anemia (low levels of red blood cells): Fatigue, loss of energy, weakness, shortness of breath, pale skin • Urinary tract infection: Pain and/or burning when urinating, blood in the urine, increased urge to urinate 	<ul style="list-style-type: none"> • Depression (feelings of sadness or hopelessness that lasts for a long time) • Respiratory tract infections: Runny or stuffy nose, sore throat, cough, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell • Vertigo (a sense of spinning dizziness)

If you are at risk of thromboembolic events, you may be closely monitored by your doctor while receiving KISQALI®

Other possible side effects of KISQALI®

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately

Very common	Common
<ul style="list-style-type: none"> • Gastroenteritis (infections of the stomach and intestines): Abdominal pain, diarrhea, nausea and vomiting • Infections: Fever, sweating or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, diarrhea or stomach pain, warm or painful areas on your body, or feeling very tired • Liver problems: Itchiness, yellow skin, nausea, vomiting, yellowing of the whites of your eyes, loss of appetite, pain in the abdomen, dark or brown urine, or more than normal bleeding or bruising • Pneumonia (infection in the lungs): Chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath 	<ul style="list-style-type: none"> • Fainting (syncope) • Febrile neutropenia: Sore throat or mouth ulcers with a single episode of fever >38.3°C (or) above 38°C for more than one hour and/or with infection • Heart problems: Chest pain or discomfort, heart palpitations, fast or slow heartbeat, dizziness, lightheadedness, fainting, sudden death • Prolongation of QT interval (Changes in the electrical system of your heart): Irregular heartbeat, fainting, loss of consciousness, seizures • Low levels of calcium: Muscle cramps and spasms, numbness and tingling in the hands, feet and face • Low levels of platelets: Spontaneous bleeding or bruising • Low levels of potassium: Irregular heartbeat, muscle weakness

3.2 Monitoring side effects

KISQALI® can cause abnormal blood test results and changes in the electrical signal of the heart. Your healthcare professional will do some tests before and during your treatment. They will tell you if your test results are abnormal and if you need treatment.



Other medications

Interactions between KISQALI® and your other medications are possible. It is therefore important to tell your healthcare team which medications you are taking.



Talk to your healthcare team

Please contact your healthcare team if you experience any of the side effects named in previous section or those listed in the package insert and if you require help dealing with these side effects. If there are any other side effects that aren't listed, contact your healthcare provider.

Talk directly to your healthcare team if side effects are so severe that you cannot continue therapy. They may be able to help manage side effects. Read in the next section what you can do yourself.

Recommendations for handling common side effects



For nausea

There are different types of nausea and vomiting that can be caused by cancer treatments including acute and delayed nausea and vomiting. Here are some practical tips and steps you can take to help manage your nausea:

- Eat foods that are easy on your stomach
- Eat foods and drink liquids at room temperature
- Slowly sip liquids throughout the day
- Suck on hard candies such as peppermints or lemon drops if your mouth has a bad taste
- Stay away from food and drink with strong smells
- Eat 5 or 6 small meals every day instead of 3 large meals
- Sip on only small amounts of liquid during meals to avoid feeling full or bloated
- Do not skip meals and snacks
- Rinse your mouth before and after eating
- Don't eat in a room that has cooking odors or that is very warm
- Sit up or lie with your head raised for one hour after eating
- Plan the best times for you to eat and drink
- Relax before each cancer treatment
- Wear clothes that are loose and comfortable
- Keep a record of when you feel nausea and why
- Talk with your doctor about using anti-nausea medicine

Please contact your healthcare team if your nausea is continuous or starts interfering with your daily life



For headache

Headaches are usually described as a throbbing, sharp, steady, or dull pain in the head.

- Take a **rest or a short nap**, preferably in a cool and dark room
- Apply a **cool compress** to your head and neck
- **Stay hydrated**
- **Eating well** can help you feel better and prevent headaches
- If the headache doesn't get better, please see your healthcare professional

You should always let your healthcare team know if you are experiencing headaches, especially if they are frequent and do not resolve. They can help you treat and manage your headaches.



For fatigue

Fatigue is a common symptom of cancer and side-effect of treatments. Below are some of the things you should keep in mind when you are experiencing fatigue:

- Make a plan that balances rest and activity. Choose activities that are relaxing for you. Light exercise may also be advised by your doctor to give you more energy and help you feel better
- Plan time to rest. If you are tired, take short naps of less than 1 hour during the day. Choose the activities that are most important to you and do them when you have the most energy. Ask for help with important tasks
- Eat and drink well. Foods high in protein and calories will help you keep up your strength. Limit your intake of caffeine and alcohol
- Meet with a specialist. It may help to meet with a counselor, psychologist, or psychiatrist. Since pain that is not controlled can also be a major source of fatigue, it may help to meet with a pain or palliative care specialist
- If fatigue becomes severe or limits your daily routines that involve taking care of yourself, such as eating or hygiene, notify your care team of the issue
- Use caution when driving or operating potentially dangerous machinery



Keep side effects in mind

During therapy with KISQALI®, side effects may also occur that are not readily apparent from certain symptoms. You will be regularly monitored for these side effects with tests such as blood tests and electrocardiograms (ECG; heart activity tests). For more information see section 3.2 Monitoring side effects on page 14 of this booklet.

For more information on KISQALI® and additional patient resources for download, visit kisqali.ca or scan the QR code

scan to visit
Kisqali.ca



3.3 Patient Support Program

Ask your healthcare professional to sign you up for the Sentia™ Patient Support Program

Starting a new treatment can be challenging. Sometimes you may feel overwhelmed with information, while at other times you may want more.

The Sentia™ Program provides ongoing personalized support designed to help you throughout your treatment journey with KISQALI®.



Once your healthcare team has enrolled you in this free program, you'll be eligible to access a number of helpful services, including:



Reimbursement and financial assistance



Dedicated nurses to answer any questions you may have



Helpful information and tools to support you

Questions?

Contact the Sentia™ Patient Support Program



1-855-736-8421 (1-855-SENTIA-1) (Mon-Fri, 8 am-8 pm EST)



1-866-636-8421



psp@sentia-exp.ca

Additional information and contacts

General information

Canadian Cancer Society

<https://cancer.ca/en/>

Canadian Breast Cancer Network

<https://cbcn.ca/en/>

BC Cancer

<http://www.bccancer.bc.ca/>

Quebec Breast Cancer Foundation

<https://rubanrose.org/en/>

Patient organizations/Self-help groups

Rethink Breast Cancer

<https://rethinkbreastcancer.com/>

Young Adult Cancer Canada

<https://youngadultcancer.ca/>

Cancer Connection

<https://www.cancerconnection.ca/s/>

Inspire

<https://www.inspire.com/groups/breast-cancer/>

Advisory service

Wellspring Cancer Support

<https://wellspring.ca/>

Canadian Cancer Society Support Line

<https://cancer.ca/en/contact-us>

1-888-939-3333

For more information on your treatment and the Sentia™ Support Program, scan the QR code or visit kisqali.ca

scan to visit
[Kisqali.ca](https://kisqali.ca)



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