

Ribociclib - letrozole

Kisqali® - Femara®

Ribociclib: Cancer-directed **targeted therapy** in tablets

Letrozole: Cancer-directed **hormonal** therapy in tablets

Understanding your treatment

What is targeted therapy?

This treatment targets specific molecules, which are inside or on the surface of cancer cells. By targeting cancer cells, the targeted therapy limits damage to healthy cells.

What is a hormonal therapy?

Hormonal therapy slows the growth of cancers that use natural hormones (for example: estrogen, progesterone and testosterone) to grow. Hormonal therapy can either stop the body from producing the hormones that cause cancer growth or it may prevent the use of the hormones by the cancer cells.

How can your treatment help you?

Depending on your type of cancer and the stage of the disease, your treatment can be used to :

- **Destroy** cancer cells
- **Stop** the cancer from spreading
- **Slow** the growth of cancer cells

How will you feel?

Not everyone has side effects and each person's experience may be different. Side effects and their severity are not representative of treatment's effectiveness or lack thereof.

This document is about the most frequent side effects caused by your treatment.

Medication

Ribociclib

Tablets to take by mouth

Letrozole

Tablets to take by mouth

Administration

To be taken once daily with or without food

Take for 21 days followed by a 7-day rest period

To be taken once daily with or without food

On a continuous basis



- A **blood test** will be done during your treatment. Depending on the results and side effects, the dose of ribociclib might be adjusted or the treatment might be delayed.
- Some tests might be done to verify the health of your **bones**. Hormonotherapy could increase the risk of developing osteoporosis and fractures. You could be prescribed vitamin D and calcium in order to maintain your bones in good condition. It is important that you eat calcium-rich foods (yogurt, cheese, milk, etc.).

How to take your medication?

Ribociclib :

- Take your ribociclib tablets as prescribed once daily at the same time every day and in the same way, either with or without food. You must take your tablets on a continuous basis for 21 days followed by a 7-day rest period.
- Tablets must be taken whole. Do not chew, split or crush the tablets.
- If you forget a dose of **ribociclib** you must not take an extra dose. You should only take the next scheduled dose and then go back to your regular schedule. However, try to take your pills at the same time every day and in the same way (with or without food).

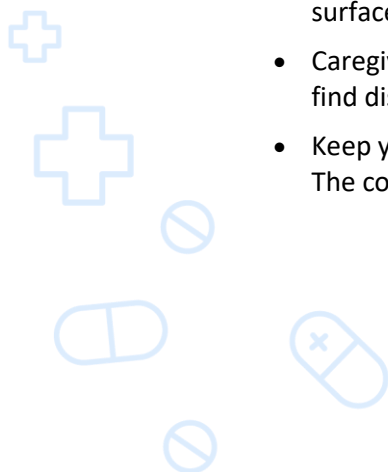
Hormonotherapy:

- Take your hormonotherapy tablets as prescribed once daily at the same time every day. You may take your medication before or during your meal with a large glass of water or juice. If you have difficulty tolerating it, for example, if it causes a stomach ache, take it while you eat.
- Tablets must be taken whole. Do not chew, split or crush the tablets.
- **If you forget a dose**, you may take it when you remember but do not double the next dose. However, try to take your pills at the same time every day.

Storing and handling your medicines



- Wash your hands immediately after handling your medication.
- Keep your medication at room temperature, out of the reach of children and pets as well as protected from light, heat or moisture. Do not keep medicines in the bathroom.
- Don't throw away unused medication at home. Bring it back to your pharmacy to be destroyed safely. You may dispose of the empty containers in your home garbage can.
- If the pills inadvertently come in contact with the surrounding surface, wash and rub the surface with water and soap.
- Caregivers should wear disposable gloves if they prepare medication for you. You can find disposable gloves at your local community pharmacy.
- Keep your medications in their original container and do not mix them with other drugs. The container should never be reused to put other objects or food.



How can this treatment affect your daily life?

Fatigue and appetite



- You may experience **fatigue** during your treatments. This is usually temporary and may be related to different reasons (medication, stress, the disease). Maintain a good level of activity but rest when you feel the need to.
- Your **appetite may diminish**. Eat more often, in smaller quantities.
- Your **sense of taste may be altered**. Enhance foods with *fines herbes* or lemon juice. Eating fruits and unsweetened candies, chewing non-sugared gums, etc., may mask the metallic taste.
- **Alcohol** in small quantities is allowed and will not affect the efficacy of the treatments.

Sex life and birth control



- You can have an **active sexual** life during your treatments. However, a decrease in your sexual drive may occur during this period. This may also be influenced by different factors (fatigue, stress, etc.).
- It's safe to kiss, to touch, to hold hands, to sleep in the same bed and to cuddle.
- It is usually not necessary for **women** to use contraception while on this treatment as it typically given to menopausal women. However, this medication could be harmful to a fetus should a pregnancy occur.

Foods and medicines to avoid



- **Grapefruit**
You must avoid consuming grapefruit, Seville oranges, starfruit, pomelo, pomegranate or foods containing them. The consumption of those foods could increase the side effects of ribociclib.



- Hormonotherapy works by decreasing the quantity of **estrogen** in your blood. It is therefore important to avoid taking products containing hormones to treat menopausal symptoms like hot flashes, vaginal dryness, etc. Some natural remedies also contain ingredients that have hormone-like effects. If you are considering taking such products, consult your pharmacist who will evaluate if it is safe for you to use them.

Tips and precautions



- **Sit down to urinate and fold down the toilet lid**
Sit down to urinate and fold down the toilet lid before flushing in order to avoid splashing. Flush twice to make sure everything has been flushed away. Follow these precautions during your treatments (or according to instructions from your cancer center).
- **Bodily fluids**
During the treatment period, it's possible that a certain quantity of the medication is found in some bodily fluids or secretions that you produce, such as urine, stools, vomit, sperm and vaginal discharge. In order to protect the environment and those living with you, follow the instructions given by your cancer center about the right way to handle

and dispose of the bodily fluids.



- **Over the counter medicines, natural health products and vaccines**

Consult your healthcare team:

- if you intend to take any other medication (with or without a prescription) or natural health products.
- if you need to receive a vaccine.

This could decrease your treatment's efficacy or increase its side effects.

- **Always have on hand the complete list of your medications**

Be sure to always have on hand the complete list of your medications, dietary supplements, vitamins and other natural health products. Give it to your doctor and your pharmacist. It is important to make them aware of any change.



What are the side effects of your treatment?

This fact sheet aims to let you know the side effects most commonly seen following the administration of your treatment. Please note that when you take any medication, there is a possibility that it causes rare side effects and it is difficult to predict which patients will be affected.

ADVERSE EFFECTS

MANAGEMENT

Decrease in white blood cells

A decrease in **white blood cells** will occur during your treatment. You may be at higher risk of infections during this period.

- Wash your hands often.
 - During this period, avoid coming into contact with people who have contagious diseases.
 - Contact a member of your healthcare team quickly if you notice any signs of infection (chills, cough, sore throat, pain while you urinate, etc.).
 - In case of fever, do not take acetaminophen (Ex: Tylenol[®], Atasol[®]) and anti-inflammatory medication (Ex: Motrin[®], Advil[®], Aleve[®]).
- ➔ **Stop ribociclib and go to the Emergency Room if:**
- you have a fever of 38,3 °C (101°F) or above
or
 - you have a fever of 38 °C (100,4 °F) twice an hour apart.

Nausea

Nausea and vomiting, usually light, may occur throughout your treatments.

- You will be prescribed medication to be taken as needed if you have nausea.
- ✔ **Continue your treatment if:** you have light nausea that does not prevent you entirely from eating. Make sure to continue your medication prescribed for your nausea.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have significant nausea, experience vomiting that is partially preventing you from eating. Make sure to continue your medication prescribed for your nausea.
- ➔ **Stop ribociclib call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe nausea or repeated vomiting that prevents you completely from eating.

Diarrhea

You may sometimes experience diarrhea.

- Drink lots of liquids (8 to 10 glasses a day) unless otherwise instructed by your doctor.
 - Eat and drink often but in small quantities.
- ✔ **Continue your treatment if:** you have light diarrhea (2 to 3 additional loose stools per day compared to usual before starting your treatment). Start loperamide (Imodium[®]) by taking 2 tablets first followed by one tablet after each loose

stool for a maximum of 8 tablets per 24-hour period.
Contact a member of your healthcare team if the diarrhea does not improve after taking loperamide for 24 hours.

⚠ Continue your treatment and call your healthcare team as soon as possible if: you experience more than 4 to 6 additional loose stools per day compared to usual before starting your treatment. Start loperamide (Imodium®) by taking 2 tablets first followed by one tablet after each loose stool for a maximum of 8 tablets per 24-hour period.

🛑 Stop ribociclib and call your healthcare team as quickly as possible or go to the Emergency Room if: you have 7 or more additional loose stools per day compared to usual before starting your treatment, if you are not able to hold it in (incontinence) or if you have diarrhea with a fever.

Hair loss

Depending on the individual, thinning of the hair may occur. However, don't worry; your hair will grow back after treatments have ended.

- Use gentle shampoo.
- In order to slow hair loss, avoid brushing hair vigorously.
- Avoid hair spray, dyes and perms.

Constipation

You may experience constipation.

- Exercise if possible.
- Drink lots of liquids (at least 8 glasses a day) (unless otherwise instructed by your doctor).
- Eat foods that are rich in fiber (cereals, fruits and vegetables).
- Communicate with a member of your healthcare team who, if necessary, will recommend appropriate laxatives.

Headaches

You may experience headaches.

- If this happens and is bothering you, talk to a member of your healthcare team who will recommend a medication for pain.
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ADVERSE EFFECTS

MANAGEMENT

Skin rash

A skin rash, usually mild, may occur during your treatment. It generally involves the trunk, the arms and legs and can be associated with itchiness.

- ✔ **Continue your treatment but contact your healthcare team if:** you develop a skin rash, such as pimples or redness **without** any itchiness or tenderness.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible:** you develop a skin rash, such as pimples or redness **with** itchiness or tenderness.
- ❌ **Stop ribociclib and call your healthcare team as quickly as possible or go to the Emergency Room if:** you develop a skin rash, such as pimples or redness all over your body with pain and your skin feels hot to the touch.

Muscle and bone pain

You may experience muscle, bone and joint pain and cramps that may occur during your treatment.

- If this happens, speak with a member of your healthcare team who will recommend an appropriate pain reliever.

Hot flashes

You may experience hot flashes. These effects vary between individuals and usually go away with time.

- If these hot flashes prevent you from doing your regular activities, take your hormonotherapy tablets at bedtime.
- Do not forget to consult your pharmacist before taking natural remedies; they could decrease the efficacy of your treatment.
- If these symptoms persist over time or are bothering you, speak with your healthcare team that will recommend appropriate measures.

Vaginal dryness

You may experience itchiness or vaginal dryness.

- If this is bothering you, consult your pharmacist who could recommend some creams.



RARE ADVERSE EFFECTS THAT CAN BE SEVERE OR SERIOUS

If the following side effects occur, stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room:

- Sensitivity or swelling of the ankles or calves
- Chest pain
- Sudden difficulty breathing

PHARMACIST: _____

PHONE: _____

FROM ____ H ____ TO ____ H ____ (MONDAY TO FRIDAY)

This fact sheet has been prepared by a sub-committee of the Comité national de l'évolution de la pratique des soins pharmaceutiques of the Programme québécois de cancérologie of the Ministry of Health and Social Services in consultation with the Comité de l'évolution de la pratique en oncologie of the Institut national d'excellence en santé et en services sociaux.

DEVELOPED **NOVEMBER 2019**



Treatment Diary | Ribociclib and letrozole 28 days

CYCLE START DATE :

LEGEND







- ✔ Continue your treatment.
- ⚠ Co Continue your treatment and contact your healthcare team as soon as possible.
- ✖ Stop **ribociclib** and contact your healthcare team without delay or go to the Emergency Room.

Refer to the information sheet for more details.

TREATMENT

(Record the dose taken)	Ribociclib:	mg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	Letrozole																													
	Date (dd-mm)																													

	DECREASE IN WHITE BLOOD CELLS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
🔴	You have a fever of 38,3°C (101°F) or above or you have a fever of 38°C (100,4°F) twice an hour apart with or without symptoms of infection.																												
	NAUSEA AND VOMITING	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
🟢	Light nausea that does not prevent you entirely from eating.																												
⚠️	Significant nausea or if you experience vomiting that is partially preventing you from eating.																												
🔴	Severe nausea or repeated vomiting that prevents you completely from eating.																												

DIARRHEA		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	Light diarrhea: you have 2 to 3 additional loose stools per day compared to usual.																												
	Moderate diarrhea: you have 4 to 6 additional loose stools per day compared to usual.																												
	Severe diarrhea: you have 7 or more additional loose stools per day compared to usual before starting your treatment or you are not able to hold it in (incontinence).																												
SKIN PROBLEMS		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	Skin problems that you did not have before such as pimples or redness, scattered on your skin but that are not itchy or tender.																												
	Skin problems that you did not have before such as pimples or redness, scattered on your skin and they itch or are tender.																												
	Skin problems that you did not have before such as pimples or redness all over your body, pain or swelling.																												