

Osimertinib

Tagrisso®

Cancer-directed targeted 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. This type of treatment can be used alone or in combination with other treatments such as chemotherapy.

How can a targeted therapy help you?

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

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

How will you feel while on a targeted therapy?

Even though those treatments target cancer cells and limit damage to healthy cells, side effects can still arise.

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

This document presents the most frequent side effects that your targeted therapy causes.

Medication

Osimertinib

Tablets to take by mouth

Administration

To be taken once daily

Take with or without food

On a continuous basis



A **blood test** will be done throughout your treatment. Depending on the results and side effects, the dose of the medication might be adjusted or the treatment might be interrupted.

How to take your medication?

- Take your osimertinib tablets as prescribed once daily, at the same time every day. You may take your medication on an empty stomach or with food and 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 as soon as you remember if less than 12 hours have passed since the missed dose. Do not double your next dose. Try to take your pills at the same time every day and in the same way (either with or without food).

Storing and handling your medicines



- Wash your hands immediately after handling your tablets.
- 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.

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.
- The effect of the drug on male or female fertility is unknown. This medication may have an effect on the menstrual cycle as well as spermatozoid production. However, this does not prevent erection or sexual activity and as such, you can have an active sexual life during your treatments. Pregnancy is possible and this medication could be harmful to the fetus. The use of an effective method of contraception is highly recommended during treatments and up to 4 months after the end of treatments for men and up to 2 months for women. Breast-feeding is contraindicated during treatment.

Tips and precautions



- **Sit down to urinate and fold down the toilet lid**
Women as well as men should 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 you 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

Skin problems

You might experience some **skin reactions** within about one or two weeks of starting your treatment. These reactions usually present with:

- A **rash** on the face, neck, chest, back, and arms. This reaction looks like acne and usually disappears within a few weeks after the end of the treatment.
- Your **skin** may become **dryer**. **Redness** and **itchiness** may develop.
- Your skin may become more **sensitive to the sun**.

To help prevent or decrease these reactions:

- Use fragrance-free, alcohol-free mild soap or cleaning products. Also use bath or shower oils to avoid skin dryness.
- Moisturize your skin twice a day with fragrance-free, thick, emollient-based creams like Aveeno®, Neutrogena® or Vaseline Intensive Care® lotion.
- Use non-perfumed creams and cosmetics without alcohol or dye. Use dermatologist-recommended make up (foundation) to mask skin problems.
- Remove make up with a mild cleaning product.
- Avoid sun exposure. In case of unavoidable sun exposure, wear a hat and clothes with long sleeves.
- Avoid over the counter acne products as they can dry skin.
- Use a broad-spectrum sunscreen (SPF of 30 or more).

If despite all these measures, skin reactions appear:


- ✓ **Continue your treatment but contact your healthcare team if:** you develop skin problems such as pimples or redness, scattered on your skin but that are not itchy or tender. Continue to apply the moisturizing cream.
- ⚠ **Continue your treatment and contact your healthcare team as soon as possible if:** you develop skin problems such as pimples or redness, scattered on your skin and they itch or are tender. Continue to apply the moisturizing cream
- ✗ **Stop your treatment and contact your healthcare team without delay or head to the Emergency Room:** if you develop skin problems, such as pimples or redness all over your body, pain or swelling.


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 hours 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 hours period.


 **Stop your treatment 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.


Ulcers in the mouth

Ulcers in the mouth may appear approximately 7 to 10 days following the start of your treatment. These ulcers can also appear in the throat.

- Gently and regularly brush your teeth after each meal and at bedtime.
- To prevent this effect, rinse your mouth with a solution of water and salt with or without baking soda or mouthwash without alcohol found in stores. Gargle 4 times a day – after every meal and at bedtime. Do not drink or eat for one hour after you gargle.

 **Continue your treatment if:** you have mild discomfort (ulcer, sensitivity, redness, irritation) that does not prevent you from eating. Continue your mouthwash.

 **Continue your treatment and call your healthcare team as soon as possible if:** you have moderate discomfort (redness and painful lesions) that prevents you from eating, but not completely. Continue your mouthwash.

 **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe discomfort and pain that is bothersome enough that it prevents you almost completely from eating.

Nausea

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

- You may be prescribed medication to prevent nausea if needed.

Nails changes

Nail changes as well as redness and

- Wear comfortable and wide shoes to avoid rubbing or pressure on the nails.

ADVERSE EFFECTS

pain around the nails may occur. This problem generally happens 4 to 8 weeks after the treatment begins.

MANAGEMENT

- Avoid nail biting and do not trim your nails too short.
- ✓ **Continue your treatment if:** you have mild redness around the nails without pain. Keep on doing the basic measures and hydrate the skin around your nails 2 to 3 times a day.
- ⚠ **Continue your treatment and call your healthcare team as soon as possible if:** you have moderate redness around the nails with or without pain that limits your daily activities. Keep on doing the basic measures and hydrate the skin around your nails 2 to 3 times a day.
- ➖ **Stop your treatment and call your healthcare team as quickly as possible or go to the Emergency Room if:** you have severe redness around the nails with pain that almost completely prevent you from doing your daily activities.

Eye problems

You may experience local irritation with or without swelling and redness around your eyes as well as blurred vision.

- Consult a member of your healthcare team who will recommend appropriate measures, if necessary.
- If possible, avoid wearing contact lenses while taking this drug.
- If you have dry eyes, you may use over the counter, preservative-free lubricating eye drops, gels or ointments 4 to 6 times a day.
- Call your healthcare team as soon as possible if your eyes are constantly painful, very red or you present with vision loss.

Hair loss

Usually there is **no hair loss** with this treatment.

Decrease in white blood cells

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

- Wash your hands often.
- 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 your treatment 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.

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:

- Cough and/or persistent fever
- Sudden difficulty breathing
- Shortness of breath
- Swelling of the ankles
- Fast or irregular heartbeats

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 2009 | REVISED NOVEMBRE 2019



Treatment Diary | Osimertinib 30 days

CYCLE START DATE:

LEGEND







-  Continue your treatment.
-  Continue your treatment and contact your healthcare team as soon as possible.
-  Stop your treatment and contact your healthcare team without delay or go to the Emergency Room.








Refer to the information sheet for more details.

TREATMENT

	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	29	30
(Record the dose taken) mg																														

Date (dd-mm)

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	29	30
 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.																														
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	29	30
 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).																														

NAILS CHANGES		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	29	30
	Mild redness around the nails without pain.																														
	Moderate redness around the nails with or without pain that limits your daily activities.																														
	Severe redness around the nails with pain that almost completely prevent you from doing your daily activities.																														
ULCERS IN THE MOUTH		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	29	30
	Mild discomfort (ulcer, sensitivity, redness, irritation) that does not prevent you from eating.																														
	Moderate discomfort (redness and painful lesions) that prevents you from eating, but not completely.																														
	Severe discomfort and pain that is bothersome enough that it prevents you almost completely from eating.																														
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	29	30
	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.																														