

Everolimus

Afinitor®

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

Everolimus

Tablets to take by mouth

Administration

To be taken once a day

With or without food

On a continuous basis



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

How to take your medication?

- Take your everolimus tablets as prescribed once every day at the same time in the same way (either always with food or always without food). You may take your pills with or without food 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 as soon as you remember if less than 6 hours have passed since the missed dose. Do not double your next dose. Try, however, 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 it inadvertently comes 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.
- For **male patients**, the production of spermatozooids may be reduced or completely absent during treatments. This reduction of fertility may be permanent, may get better or return to normal after the treatments have stopped. This reduction of **fertility** does not prevent erection or sexual activity and a pregnancy remains possible.
- The treatment may affect the sperm and it may be harmful to the embryo.
 - If you have sex with a woman of child-bearing age, a birth control method is strongly recommended during treatment.
 - Notify your doctor immediately if you had unprotected sex and your partner is pregnant.
- In **pre-menopausal female patients** everolimus may cause the menstrual cycle to be irregular or stop completely during treatment. The menstrual cycle may restart or return to normal after the end of treatment. The menstrual cycle may also stop permanently. However, a pregnancy remains possible and chemotherapy administered during pregnancy may harm the embryo.
 - A birth control method is strongly recommended during treatment and up to 8 weeks after the end of treatment.
 - Breast-feeding is not recommended during treatment.

Foods to avoid



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

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 your treatment, it's possible that a certain quantity of your 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

Ulcers in the mouth

Ulcers in the mouth may appear approximately 1 to 2 weeks 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.
- Cortisone mouthwash may also be prescribed to prevent this effect.
- ✓ **Continue your treatment if:** you have mild discomfort (ulcer, sensitivity, redness, irritation) that does not prevent you from eating. Continue your mouthwash.
- ⚠ **Stop 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, if you notice more than 3 lesions (ulcers), if the lesions last more than 3 days or if pain is severe or if you cannot eat.
- ✗ **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.

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 **drier**. **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 your 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 your 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.



ADVERSE EFFECTS

MANAGEMENT

Nausea

Nausea and vomiting, usually light, may occur during your treatment.

- You may 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 your treatment and 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.

Fluid retention

A gradual fluid retention may occur with your treatment and may present itself by swelling of the hands, ankles and feet.

- Raise your feet while sitting.
- Avoid wearing tight clothes or shoes.
- Notify a member of your healthcare team if you are gaining weight rapidly, if you experience some swelling or if you are easily short of breath.

Decrease in white blood cells

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

- Wash your hands often.
- During this period, avoid coming in 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.

Decrease in platelets

A decrease in platelets may occur during treatment. You may bruise or bleed more easily than you normally do.

- Use a tooth brush with soft bristles.
- Consult your pharmacist before taking over the counter medications containing Aspirin® or other anti-inflammatory medication (e.g. Advil®, Motrin®, Aleve®, etc.).

ADVERSE EFFECTS

MANAGEMENT

- Contact a member of your healthcare team if you bruise more easily than you normally do or if you have a tendency to bleed easily from the nose or the gums.

Hair loss

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

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:

- Sudden difficulty breathing
- Cough and/or persistent fever

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 FEBRUARY 2013 | REVISED NOVEMBER 2019



Treatment Diary | Everolimus 28 days






CYCLE START DATE :

LEGEND

- ✔ Continue your treatment.
- ⚠ Continue (***except for ulcers : stop**) 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

		DAYS OF CYCLE																											
(Record the dose taken)		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
Everolimus mg																													
Date (dd-mm)																													
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
✔	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.																												
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.																												
	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).																												
	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.																												
	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.																												