

Vismodegib

Erivedge®

Cancer-directed targeted therapy in capsules

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

Vismodegib

Capsules to take by mouth

Administration

To be taken once daily

With or without food

On a continuous basis



- A **blood test** will be done regularly. If necessary, the dose of vismodegib may be adjusted or the treatment may be delayed depending on the blood test results or on the side effects that you may have had with the previous treatment.
- **Pre-menopausal woman:** a blood test will be required before the start of treatment to assess whether or not you are pregnant. The blood test will be mandatory every month thereafter.

How to take your medication?

- Vismodegib is distributed by a pharmacy different from your usual pharmacy.
- Take your vismodegib capsule as prescribed once a day at the same time every day. You may take your capsules 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.
- Capsules must be taken whole. Do not open or crush the capsules.
- If you forget a dose, you should not take an extra dose. You should just take the next dose according to your usual schedule. 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 capsules.
- 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.
- Pour the capsules from the container into the cap to avoid contact with other surfaces. 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. The container should never be reused to put other objects or food.

How can this treatment affect your daily life?

Appetite

- 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.
- **Pre-menopausal women** must use **two different contraceptive methods** including a mechanical barrier with spermicide. You must start using them at least 4 weeks prior to the beginning of vismodegib, during the treatment and for up to 2 years after the end of the treatment. Vismodegib may cause **birth defects** or fetal death. Avoid taking vismodegib if you are pregnant or trying to get pregnant. If you cannot use hormonal contraception (implants or injections), you must use 2 mechanical barriers with spermicide (condom, diaphragm, cervical cap, contraceptive sponge).
- Breast-feeding is contraindicated during treatment until 2 years after the end of the treatment.
- **Men** must use a condom with a spermicide if they have sex with a pre-menopausal woman for the total duration of treatment and up to 2 months after the end of the treatment. This is a necessary measure even in men who have had a vasectomy.
- If you had unprotected sex or if your partner is pregnant: notify your doctor immediately.

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 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

Muscle, bone pain and joint pain

You may experience muscle, bone and joint pain and muscle spasms and cramps. It may occur during your treatment and up to many months after the end of treatment.

- If these symptoms occur and bother you, consult a member of your healthcare team who will suggest appropriate medication for pain.

Hair loss

Depending on the individual, a partial or total hair loss 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.

Fatigue

You may experience fatigue with or without weakness during your treatments. This is usually temporary and may be related to different reasons (medication, stress, the disease, dehydration, ...)

- Maintain a good level of activity but rest when you feel the need to.

Nausea

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

- You might be prescribed medication to be taken as needed if you have nausea.
- Contact a member of your healthcare team if you have nausea that bothers you.

Diarrhea

You may sometimes experience diarrhea.

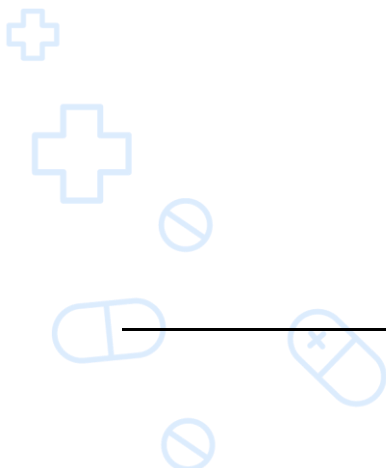
- Drink lots of liquids (8 to 10 glasses a day) unless otherwise instructed by your doctor.
- Eat and drink often but in small quantities.




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.

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.

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:

- Irregular or fast heartbeat, chest pain
- Pain in your calf or leg with local skin warmth and redness or sudden difficulty breathing
- Weakness or numbness on face, arms or legs, difficulty talking or understanding what others are saying, vision problems (blurred or double vision), dizziness and loss of balance

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.

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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 detail.

		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
mg																													
Date (dd-mm)																													
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).																												