

Medication Information Sheet**vemURAFenib** (VEM-ue-RAF-e-nib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Zelboraf®

Appearance: tablet

What is this medication for?

For treating a type of skin cancer called melanoma that has spread to other parts of the body or cannot be removed by surgery.

What should I do before I have this medication?

- Tell your doctor or pharmacist if you have or had significant medical condition(s), such as:
 - ◊ any heart problems (including irregular heartbeat)
 - ◊ eye, liver or kidney problems
 - ◊ low blood levels of potassium, calcium or magnesium
 - ◊ high blood pressure
 - ◊ other cancers (prior or current)
 - ◊ any nerve problems associated with diabetes
 - ◊ any allergies
- Tell your doctor or health care provider if you have received radiation treatment in the past, or are planning to receive radiation treatment. Vemurafenib may increase your body's sensitivity to radiation therapy.
- People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding.
- If there is ANY chance that you or your partner may become pregnant, you and your partner

together must: ► **Use 2 effective forms of birth control at the same time** while taking this drug. Keep using birth control for at least **6 months** after your last dose. Discuss with your health care team.

- Do not breastfeed while taking this medication.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- Vemurafenib is usually taken twice a day, in the morning and in the evening, about 12 hours apart.
- Do not crush or chew the tablets.
- Swallow whole with a glass of water, consistently with or without food.
- If you vomit after taking a dose, do not take an additional dose. Continue to take your next dose at the usual time.
- If you miss a dose, take it as soon as you remember. If it is within 4 hours of your next scheduled dose, just take your next dose as scheduled. Do not double the dose to make up for the forgotten one.

What else do I need to know while on this medication?

- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.
- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements), such as antibiotics, antifungals, seizure medications, heart medications and St. John's wort. Check with your health care team before starting or stopping any of them.
- For mild aches and pain:
 - ◊ You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - ◊ Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding.
 - ◊ Talk to your health care team before you start or stop these medications.
 - ◊ If you feel unwell, take your temperature before taking any of these medications. They may hide a fever.

*The most updated version and more symptom control information can be found on: <http://www.cancercare.on.ca/druginfo>

Prepared with input from the Cancer Care Ontario-Medication Information Sheets Working Group.

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- **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.
- Limit use of caffeine (coffee, tea, cola) as this may cause side effects.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

| Side effects and what to do | When to contact doctor? |
|---|--|
| Very Common Side Effects (50 or more out of 100 people) | |
| Headache; mild joint, muscle pain or cramps <ul style="list-style-type: none"> • Take your pain medication as prescribed by your doctor. • You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. • Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. • Rest often and try light exercise as it may help. | Contact your health care team if no improvement or if severe |

| Side effects and what to do | When to contact doctor? |
|---|-------------------------|
| Common Side Effects (25 to 49 out of 100 people) | |
| Hair thinning or loss <ul style="list-style-type: none"> • Use a gentle soft brush and avoid hair sprays, bleaches, dyes and perms. • In most cases, your hair will grow back after treatment, but the texture or colour may change. | |

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| Side effects and what to do | When to contact doctor? |
|--|---|
| Common Side Effects (25 to 49 out of 100 people) | |
| <p>Fatigue (tiredness)</p> <ul style="list-style-type: none"> • Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). • Avoid driving or using machinery if you are feeling tired <p>See our Fatigue pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p> |
| <p>Skin sensitivity to sunlight (may be severe)</p> <p>Your skin may be more sensitive to the sun. You can have an itchy rash and other skin reactions when you are exposed to the sun.</p> <ul style="list-style-type: none"> • Try to stay out of the sun if you can. • Apply sunscreen with UVA and UVB protection and an SPF of at least 30. • Use a lip balm with sunscreen for your lips. • When you are in the sun, wear long sleeved shirts, long pants and a hat to protect yourself. • Use a daily moisturizer on your skin. | <p>Contact your health care team if no improvement or if severe</p> |
| <p>Rash; dry, itchy skin; tender skin nodules</p> <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p> <p>To prevent and treat dry skin,</p> <ul style="list-style-type: none"> • Use skin moisturizer. • Protect your skin from the sun and the cold. • Use sunscreen with UVA and UVB protection and a SPF of at least 30. | <p>Contact your health care team if no improvement or if severe</p> |
| <p>Abnormal kidney lab tests (may be severe)</p> <ul style="list-style-type: none"> • Signs of a kidney problem include swelling, passing very little or no pee, or new unusual weight gain. If you have these signs, call your health team or go to your closest emergency department. • To prevent bladder or kidney problems, drink lots of water or other liquids. Your doctor may ask you to drink at least 6 to 8 cups (2 L) per day on treatment days, unless you have been told otherwise. • Your doctor may check your kidney function regularly. | <p>Contact your health care team if no improvement or if severe</p> |

| Side effects and what to do | When to contact doctor? |
|--|---|
| Common Side Effects (25 to 49 out of 100 people) | |
| <p>Nausea and vomiting (generally mild)</p> <p>May occur in hours to days after your treatment.</p> <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. <p>Also see Nausea & Vomiting pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p> |
| <p>Diarrhea</p> <p>May happen days to weeks after you get your treatment.</p> <p>If you have diarrhea :</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it. • Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. <p>See the Diarrhea pamphlet for more information.</p> | <p>Contact your health care team if no improvement or if severe</p> |
| <p>Second cancers (may be severe), growth of pre-existing cancers</p> <ul style="list-style-type: none"> • Check your skin on a regular basis for any skin changes. <p>Your doctor may inspect your head, neck, mouth and lymph glands, in case a cancer lesion would develop. Genital and anal exams may also be done to detect any skin changes.</p> | <p>Contact your health care team if no improvement or if severe</p> |

| Side effects and what to do | When to contact doctor? |
|--|--|
| Less Common Side Effects (10 to 24 out of 100 people) | |
| <p>Low appetite</p> <ul style="list-style-type: none"> You may not feel like eating or you may lose weight. Try to eat foods that you like and eat small meals throughout the day. You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have a low appetite. See our Loss of appetite pamphlet for more information. | Contact your health care team if no improvement or if severe |
| <p>Mild swelling in arms and legs; puffiness</p> <p>To help prevent swelling :</p> <ul style="list-style-type: none"> Eat a low-salt diet. Avoid tight fitting clothing. <p>If you have swelling in your legs, keep your feet up when sitting.</p> | Contact your health care team if no improvement or if severe |
| <p>Taste changes</p> <ul style="list-style-type: none"> Eat food that needs less chewing. Taste foods at different temperatures, since the flavor may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. | Contact your health care team if no improvement or if severe |
| <p>Constipation</p> <p>To help prevent constipation :</p> <ul style="list-style-type: none"> Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. Be Active. Exercise can help to keep you regular. Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation :</p> <ul style="list-style-type: none"> If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do. <p>See the Constipation Pamphlet for more information.</p> | Contact your health care team if no improvement or if severe |
| <p>Cough; feeling short of breath</p> <p>You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose.</p> | Contact your health care team if no improvement or if severe |

| Side effects and what to do | When to contact doctor? |
|--|--|
| Less Common Side Effects (10 to 24 out of 100 people) | |
| Abnormal liver lab tests (may be severe) <ul style="list-style-type: none"> You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. Your doctor may monitor your liver regularly with a blood test. | Contact your health care team if no improvement or if severe |
| Fever (not related to infection) <ul style="list-style-type: none"> For mild fever, you may be instructed to take acetaminophen (Tylenol®) as directed. | Contact your health care team if no improvement or if severe |
| Pains or cramps in the belly <ul style="list-style-type: none"> If you have constipation or diarrhea it may be causing the pain in your belly. If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. | Contact your health care team if no improvement or if severe |
| Trouble falling asleep <ul style="list-style-type: none"> This may be caused by one of your medications and may improve once your body gets used to the medication or when your treatment ends. Talk to your doctor if this bothers you. | Contact your health care team if no improvement or if severe |
| Dizziness <ul style="list-style-type: none"> You may feel light-headed. Lay down if this happens. Get up and move slowly once you feel better. Do not drive a motor vehicle or use machinery if you feel dizzy. | Contact your health care team if no improvement or if severe |

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Pain, swelling and hardening of a vein in your arm or leg
- Chest pain, irregular heartbeat or pain in your belly or arm
- Severe rash, itchiness, swollen face, lip or tongue, chest or throat tightness
- Red or purple patches on your skin, rash/patches that do not turn white when pressed
- Reactions at sites of previous radiation, such as rash and blistering of your skin
- Blurred vision or other changes in your vision
- Thickening of tissue under the palms of your hands or soles of your feet that cause tightening of your fingers or pain while walking

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For more links on how to manage your symptoms go to www.cancercare.on.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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