



Provincial Health Services Authority

For the Patient: **SMAVVEM**

Other Names: Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma Using Vemurafenib

SM = Skin and Melanoma

AV = Advanced

VEM = Vemurafenib

ABOUT THIS MEDICATION

What is this drug used for?

- Vemurafenib (vem" ue raf' e nib) is a drug that is used to treat a type of skin cancer called melanoma,
 - that has spread to other parts of the body or cannot be removed by surgery, and
 - that has a certain type of abnormal "BRAF" gene

How does this drug work?

- Vemurafenib targets proteins made from the abnormal BRAF gene and slows down or stops the growth of cancer cells.

INTENDED BENEFITS

- Vemurafenib is being given to destroy and/or limit the growth of melanoma cells. It may improve your current symptoms, and delay or prevent the onset of new ones.

TREATMENT SUMMARY

How are these drugs given?

- Vemurafenib is a tablet that you take by mouth.
- Vemurafenib is taken twice daily, continuously, as long as you are benefiting from treatment and not having too many side effects.

What will happen when I get my drugs?

- "BRAF" gene test of your cancer is done before starting treatment.
- A blood test (lab work) and other tests are done before starting treatment and each time you see your oncologist.
- The dose may be changed or interrupted based on your test results and/or side effects.

INSTRUCTIONS FOR THE PATIENT

How should I store this drug?

- **Store** vemurafenib tablets out of the reach of children, at room temperature, away from heat, light, and moisture. It is best to keep vemurafenib in its original packaging.

How should I take this drug?

- Vemurafenib is taken twice daily, in the morning and in the evening, approximately 12 hours apart.
- You may **take** vemurafenib with food or on an empty stomach.
- Do not chew or crush vemurafenib tablets. **Swallow whole.**
- If you **miss a dose** of vemurafenib, take it as soon as you can if it is within 8 hours of the missed dose. If it is more than 8 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of vemurafenib, skip the dose and go back to your usual dosing times. Do NOT repeat the dose. Let your doctor know as a medication to prevent nausea may be required for future doses.

What other drugs or foods can interact with Vemurafenib?

- Other drugs such as warfarin (COUMADIN®) and medicines for heart rhythm problems (i.e., quinidine, amiodarone) may **interact** with vemurafenib. Tell your doctor if you are taking this or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- **Avoid grapefruit and grapefruit juice** for the duration of your treatment, as these may interact with vemurafenib.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of vemurafenib.

Other important things to know:

- Before you start taking Vemurafenib, talk to your doctor or pharmacist if you have any heart problems, including a condition called long QT syndrome.
- Vemurafenib may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with vemurafenib and for 6 months after treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
- **Tell** doctors or dentists that you are being treated with vemurafenib before you receive any treatment from them.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Are there any risks?

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

SERIOUS SIDE EFFECTS	How common is it?	MANAGEMENT
<p>Abnormal heart rhythm (QT prolongation) rarely occurs.</p>	<p>Rare</p>	<p>Minimize your risk of abnormal heart rhythm by:</p> <ul style="list-style-type: none"> • always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement • avoiding grapefruit and grapefruit juice <p>Contact your doctor <i>immediately</i> or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded, or dizzy.</p>
<p>Skin cancer called cutaneous squamous cell carcinoma (cuSCC) may occur.</p>	<p>Common</p>	<p>Check your skin and tell your oncologist right away about any skin changes including a:</p> <ul style="list-style-type: none"> • new wart • skin sore or reddish bump that bleeds or does not heal • change in size or color of a mole <p>Cutaneous squamous cell carcinoma is typically managed with simple excision.</p>
<p>Allergic reactions may rarely occur. Signs of an allergic reaction may include flushing, rash, itching, dizziness, swelling or breathing problems.</p>	<p>Rare</p>	<p>Contact your doctor <i>immediately</i> or get emergency help if this happens after you start taking vemurafenib.</p>

SERIOUS SIDE EFFECTS	How common is it?	MANAGEMENT
<p>Reactions at sites of radiation (radiation sensitization and recall) including:</p> <p>Severe skin reactions (skin rash, blistering, peeling or discoloration of the skin)</p>	Rare	Avoid radiation therapy during treatment with vemurafenib and cobimetinib unless advised by your oncologist.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment. Most people have little or no nausea.</p>	Rare	<p>You may be given a prescription for anti-nausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. <p>Try the ideas in <i>Food Choices to Help Control Nausea</i>.*</p>
<p>Skin rashes or dry skin may sometimes occur.</p>	Common	<ul style="list-style-type: none"> • If rash is accompanied by signs of an allergic reaction such as flushing, dizziness, swelling, or breathing problems, call your doctor immediately. • If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
<p>Fever may sometimes occur.</p>	Uncommon	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Diarrhea may sometimes occur.	Common	If diarrhea is a problem: <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. Avoid high fibre foods as outlined in <i>Food Ideas to Help Manage Diarrhea</i> .*
Constipation may sometimes occur.	Uncommon	If constipation is a problem: <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. Try ideas in <i>Suggestions for Dealing with Constipation</i> .*
Headache may sometimes occur.	Common	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may commonly occur.	Very Common	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	Uncommon	If swelling is a problem: <ul style="list-style-type: none"> • Elevate your feet when sitting. • Avoid tight clothing.
Taste alteration may sometimes occur.	Uncommon	Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i> .*
Loss of appetite and weight loss may occur.	Uncommon	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Tiredness and lack of energy may commonly occur.	Common	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. • Try the ideas in <i>Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue</i>.*

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Hair loss sometimes occurs with vemurafenib. Hair will grow back once you stop treatment with vemurafenib. Colour and texture may change.	Common	If hair loss is a problem, refer to <i>For the Patient: Hair Loss Due to Chemotherapy</i> .*
Your skin may sunburn more easily than usual.	Common	<p>To help prevent sunburn:</p> <ul style="list-style-type: none"> ○ Avoid unnecessary exposure to UV light including sunlight, tanning beds, and sun lamps. ○ When outside, cover up with a long-sleeved shirt, long pants or skirt and a broad-brimmed hat made out of tightly woven, dark coloured fabric. ○ Use a broad-spectrum sunscreen (protects against both UVA and UVB) that has a sun protection factor (SPF) of at least 30. <ul style="list-style-type: none"> ● Refer to <i>Your Medication Sun Sensitivity and Sunscreens*</i> or the <i>BC Health Guide</i> for more information. ● After sun exposure, if you have severe sunburn or skin reaction such as itching, rash, or swelling, contact your doctor.
Numbness or tingling of the fingers or toes may rarely occur. This will slowly return to normal once your treatments are over.	Rare	<ul style="list-style-type: none"> ● Be careful when handling items that are sharp, hot, or cold. ● Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects.

***Please ask your oncologist or pharmacist for a copy.**

THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING VEMURAFENIB AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** (rare) soon after a treatment including rash, dizziness, fast heart beat, face swelling, or breathing problems.
- Signs of **heart problems** such as fast or uneven heartbeat, shortness of breath, dizziness, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- **Numbness or tingling** in feet or hands.
- **Changes in eyesight, eye pain, or sensitivity to light.**
- **Scaly or crusted** areas on the skin, skin **sores** that do not heal, or any change in warts or moles

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Uncontrolled nausea, vomiting, or diarrhea.
- Headache not controlled with acetaminophen (e.g., **TYLENOL®**).
- Skin rash, redness, or itching.

If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:

_____ at telephone number: _____