

## Medication Information Sheet

**vismodegib** (VIS-mo-DEG-ib)

*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:** Erivedge®

**Appearance:** capsule

**What is this medication for?**

- For treating a type of skin cancer (basal cell carcinoma) not appropriate for surgery or radiotherapy, or has spread to other parts of the body

**What should I do before I have this medication?**

- Tell your health care team if you have or had significant medical condition(s), especially if you have / had:
  - ◊ liver or gallbladder problems
  - ◊ pancreas problems
  - ◊ kidney problems
  - ◊ any allergies
- Your doctor and pharmacy must be registered with Erivedge® Pregnancy Prevention Program.
- You must register with and follow the requirements of the Erivedge® Pregnancy Prevention Program before taking vismodegib.
- This drug contains a small amount of lactose. If you cannot tolerate lactose, talk to your health care team
- 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

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

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together must:

- ► Use 2 effective forms of birth control at the same time while taking this drug AND have regular pregnancy tests. (see the Erivedge® program for full details of requirements). Discuss with your healthcare team.
- Do not breastfeed while taking vismodegib and for 24 months after the last dose.
- Some females taking vismodegib have stopped having periods. It is not known if the periods will come back. Talk to your doctor if you wish to have children in the future.
- This medication may affect fertility (ability to get pregnant).

## How is this medication given?

- This medication is usually taken once a day by mouth.
- Take the dose at about the same time each day.
- Swallow whole with a glass of water, with or without food.
- If you miss a dose, skip this and take your next dose as you normally do. Do not take an extra dose to make up for the missed dose.
- Do not crush or open the capsules, as this may increase side effects.

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

- 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). Check with your health care team before starting or stopping any of them.
- 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.
- 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.

- **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.
- Do not donate blood while taking vismodegib and for 24 months after the last dose.
- Do not donate semen during treatment and for 2 months after stopping therapy.

## 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?
<b>Very Common Side Effects (50 or more out of 100 people)</b>	
<p><b>Mild joint, muscle pain or cramps; Headache (less common)</b></p> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul> <p>Rarely these symptoms may persist for many months even after you stop your treatment.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Hair thinning or loss</b></p> <ul style="list-style-type: none"> <li>• Use a gentle soft brush and avoid hair sprays, bleaches, dyes and perms.</li> <li>• In most cases, your hair will grow back after treatment, but the texture or colour may change.</li> </ul>	

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<b>Very Common Side Effects (50 or more out of 100 people)</b>	
<p><b>Taste changes</b></p> <ul style="list-style-type: none"> <li>• Eat food that needs less chewing.</li> <li>• Taste foods at different temperatures, since the flavor may change.</li> <li>• Try different forms of foods, like fresh, frozen or canned.</li> <li>• Experiment with non-spicy foods, spices and seasonings.</li> </ul> <p>Rarely these symptoms may persist for many months even after you stop your treatment.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<p><b>Low appetite, weight loss</b></p> <ul style="list-style-type: none"> <li>• You may not feel like eating or you may lose weight.</li> <li>• Try to eat foods that you like and eat small meals throughout the day.</li> <li>• You may need to take meal supplements to help keep your weight up.</li> <li>• Talk to your health care team if you have a low appetite.</li> <li>• See our <a href="#">Loss of appetite</a> pamphlet for more information.</li> </ul> <p>Rarely these symptoms may persist for many months even after you stop your treatment.</p>	Contact your health care team if no improvement or if severe
<p><b>Fatigue (tiredness)</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Pace yourself, do not rush. Put off less important activities. Rest when you need to.</li> <li>• 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).</li> <li>• Avoid driving or using machinery if you are feeling tired</li> </ul> <p>See our <a href="#">Fatigue</a> pamphlet for more information.</p>	Contact your health care team if no improvement or if severe
<p><b>Changes in your menstrual periods</b></p> <p>You may have changes in your menstruation cycle (periods) or menstruation flow (heavy or light periods).</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common Side Effects (25 to 49 out of 100 people)</b>	
<p><b>Nausea and vomiting (generally mild)</b></p> <p>May occur in hours to days after your treatment.</p> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take anti-nausea medication(s) as prescribed to you by your doctor.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (e.g. coffee, tea) and alcohol.</li> <li>• Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting.</li> </ul> <p>Also see <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Salt imbalances</b></p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	<p>Get emergency medical help right away</p>
<p><b>Diarrhea</b></p> <p>May happen days to weeks after you get your treatment.</p> <p><b>If you have diarrhea :</b></p> <ul style="list-style-type: none"> <li>• Take anti-diarrhea medication if your health care team prescribed it.</li> <li>• Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol.</li> <li>• Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>• 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.</li> </ul> <p>See the <a href="#">Diarrhea</a> pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Abnormal liver lab tests (may be severe)</b></p> <ul style="list-style-type: none"> <li>• Your doctor may monitor your liver regularly with a blood test but you may not have any symptoms.</li> <li>• Rarely this may be severe and 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 right away (urgently) if this happens.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<p><b>Constipation</b></p> <p><b>To help prevent constipation:</b></p> <ul style="list-style-type: none"> <li>• Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise.</li> <li>• Be Active. Exercise can help to keep you regular.</li> <li>• 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.</li> </ul> <p><b>To help treat constipation:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>See the <a href="#">Constipation</a> Pamphlet for more information.</p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Cough; feeling short of breath (rarely may be severe)</b></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> <p><b>If you have severe chest pain, shortness of breath or are coughing up blood you should seek emergency medical help right away.</b></p>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Abnormal kidney lab tests (may be severe)</b></p> <ul style="list-style-type: none"> <li>• 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 care team or go to your closest emergency department.</li> <li>• 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.</li> <li>• Your doctor may check your kidney function regularly.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Trouble falling asleep</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Talk to your doctor if this bothers you.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>
<p><b>Fever, chills, infection</b></p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p>	<p>Get emergency medical help right away</p>

Side effects and what to do	When to contact doctor?
<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<ul style="list-style-type: none"> <li>• <b>38.3°C (100.9°F) or higher at any time OR</b></li> <li>• <b>38.0°C (or 100.4°F) or higher for at least one hour.</b></li> </ul> <p>While you are taking vismodegib:</p> <ul style="list-style-type: none"> <li>• Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills).</li> <li>• Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever.</li> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> <li>• Wash your hands often.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> </ul> <p><b>If you have a fever, talk to your health care team or go to the closest emergency room.</b></p>	

**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:**

- new growths on your skin
- trouble speaking, difficulty using your arms or legs, confusion or fainting
- chest pain, irregular heartbeat
- pain, swelling and hardening of the vein in an arm or leg
- severe belly pain
- vomiting blood or what looks like coffee-grounds; stool (poo) that is black/tarry coloured or has bright red blood in it
- having paranoid thoughts
- severe muscle pain or weakness

*For more links on how to manage your symptoms go to [www.cancercare.on.ca/symptoms](http://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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