Vismodegib (vis" moe deg' ib) is a drug that is used to treat some types of cancer. It is a capsule that you take by mouth. The capsule contains lactose.

Tell your doctor if you have ever had an unusual or allergic reaction to vismodegib before taking vismodegib.

Before receiving vismodegib you will be registered with the ERIVEDGE® Pregnancy Prevention Program, a distribution control program run by the manufacturer of vismodegib.

A blood test may be taken before each treatment. The dose and timing of your chemotherapy may be changed based on the test results and/or other side effects.

If you are a woman and are able to bear children, a blood test to determine whether you are pregnant will be taken before starting vismodegib treatment, every month during treatment (including dose interruptions), and for 24 months after you stop treatment.

Vismodegib may harm the baby if used during pregnancy. Severe birth defects to the unborn baby may occur. Two forms of reliable birth control must be used at the same time during treatment and for 24 months after your last dose of vismodegib. Tell your doctor right away if you become pregnant. Do not breast feed during treatment.

Men who are taking vismodegib must use a condom with spermicide every time they have sex with a female partner who is able to bear children. A condom must be used during treatment (including dose interruptions), and for 2 months after your last dose of vismodegib. This is because the drug may be present in semen. Do not donate semen while you are taking vismodegib and for 2 months after your last dose of vismodegib. Tell your doctor right away if your partner becomes pregnant.

Vismodegib may cause sterility in men and menopause in women. If you plan to have children, discuss this with your doctor before being treated with vismodegib.

Do not donate blood while you are taking vismodegib and for 24 months after your last dose of vismodegib.

It is important to take vismodegib exactly as directed by your doctor. Make sure you understand the directions.

You may take vismodegib with food or on an empty stomach.
• If you miss a dose of vismodegib, skip the missed dose and go back to your usual dosing times. Do not take any doses to make up for the missed dose.

• Other drugs may interact with vismodegib. Check with your doctor or pharmacist before you start or stop taking any other drugs.

• The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of vismodegib.

• Store vismodegib capsules out of the reach of children, at room temperature, away from heat, light, and moisture.

• Tell doctors, dentists, and other health professionals that you are being treated with vismodegib before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

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<tr>
<th>SIDE EFFECTS</th>
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| Nausea and vomiting may occur with vismodegib. Most people have little or no nausea. | You may be given a prescription for antinausea drug(s) to take at home. **It is easier to prevent nausea than treat it once it has occurred**, so follow directions closely.  
  • Drink plenty of fluids.  
  • Eat and drink often in small amounts.  
  • Try the ideas in **Food Choices to Help Control Nausea**.* |
| Diarrhea may sometimes occur.        | If diarrhea is a problem:  
  • Drink plenty of fluids.  
  • Eat and drink often in small amounts.  
  • Avoid high fibre foods as outlined in **Food Ideas to Help Manage Diarrhea**.*  
  • Note: If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take LACTAID® tablets just before your vismodegib dose. |
| Constipation may sometimes occur.    | • Exercise if you can.  
  • Drink plenty of fluids.  
  • Try ideas in **Suggestions for Dealing with Constipation**.* |
### SIDE EFFECTS | MANAGEMENT
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**Muscle or joint pain** may sometimes occur. | 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.

You may sometimes have **trouble sleeping**. | • Talk to your doctor if you continue to have trouble sleeping.
• This will return to normal when you stop taking vismodegib.

**Taste alteration** commonly occurs. | Try the ideas in *Food Ideas to Cope with Taste and Smell Changes.*

**Loss of appetite** and **weight loss** may sometimes occur. | Try the ideas in *Food Ideas to Help with Decreased Appetite.*

**Tiredness** and lack of energy may sometimes occur. | • Do not drive a car or operate machinery if you are feeling tired.
• Try the ideas in *Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.*

**Hair loss** is common and may begin within a few days or weeks of treatment. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change. | Refer to *For the Patient: Hair Loss Due to Chemotherapy.* You may also want to:
• Apply mineral oil to your scalp to reduce itching.
• If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-rimmed hat and glasses.

*Please ask your chemotherapy nurse or pharmacist for a copy.

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

- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine.
- Severe **abdominal pain**.
SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower legs.
- Signs of skin changes such as a new wart, a sore or reddish bump that bleeds or does not heal, or a change in size, shape, or colour of a mole.
- Signs of an infection such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, runny nose, productive cough (coughing up thick or green sputum); or cloudy or foul smelling urine.

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

- Uncontrolled nausea, vomiting, or diarrhea.
- Headache or pain not controlled with acetaminophen (e.g., TYLENOL®).
- Muscle spasms.
- Dry skin, rash, or itching.
- Numbness or tingling in feet or hands.
- Feelings of anxiety or depression.
- Dizziness.
- Upset stomach or flatulence (passing gas).
- Trouble swallowing.
- Cough.
- Abnormal menstrual bleeding.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR