PRODUCT MONOGRAPH

# PrERIVEDGE®

vismodegib

Capsule, 150 mg

Antineoplastic agent

Hoffmann-La Roche Limited
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**PART III: CONSUMER INFORMATION**

# PrERIVEDGE®
vismodegib

This leaflet is part III of a three-part "Product Monograph" published when ERIVEDGE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ERIVEDGE. Contact your doctor or pharmacist if you have any questions about the drug.

## ABOUT THIS MEDICATION

**ERIVEDGE can only be given to patients who are registered in and meet all conditions of the ERIVEDGE Pregnancy Prevention Program (EPPP), which is a controlled distribution program for ERIVEDGE.**

What the medication is used for:
ERIVEDGE is used to treat adults with a type of skin cancer called advanced basal cell carcinoma (BCC). It is used when the cancer:

- has spread to other parts of the body (called "metastatic" basal cell carcinoma)
- has spread to surrounding areas (called "locally advanced" basal cell carcinoma) and your doctor decides that it cannot be treated with surgery or radiation.

What it does:
DNA in skin cells can become damaged. This damage can change how certain proteins in a cell work and turn those cells into skin cancer. ERIVEDGE works by controlling a key protein involved in cancer. This may slow or stop the cancer cells from growing, or may kill them. As a result, your skin cancer may shrink.

When it must not be used:

- if you are pregnant, think you may be pregnant, or are planning to become pregnant,
- if you are breastfeeding,
- if you are able to become pregnant but are unable or unwilling to follow the necessary pregnancy prevention measures that are listed in the EPPP,
- if you are male and are unable or unwilling to follow the necessary contraceptive measures listed in the EPPP,
- if you are less than 18 years of age,
- if you are allergic to vismodegib or any of the other ingredients of this medicine

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking ERIVEDGE.

What the medicinal ingredient is:
vismodegib

What the non-medicinal ingredients are:
Capsule content: microcrystalline cellulose PH101; lactose monohydrate; magnesium stearate; sodium lauryl sulfate; povidone K29/32; sodium starch glycolate; talc.

Capsule shell (body): gelatin; titanium dioxide; iron oxide red.
Capsule shell (cap): gelatin; titanium dioxide; iron oxide black.

Printing ink: includes shellac and iron oxide black.

What dosage forms it comes in:
Capsule, 150 mg

ERIVEDGE is a grey/pink two-piece hard gelatin capsule with "VISMO" printed on the grey cap and "150 mg" printed on the pink body in black edible ink. ERIVEDGE is supplied in high density polyethylene (HDPE) bottles (28 capsules per bottle).

## WARNINGS AND PRECAUTIONS

**Serious Warnings and Precautions**

- **ERIVEDGE treatment should be started and monitored only under the supervision of a physician qualified in the use of cancer therapies and with a full understanding of the risks of ERIVEDGE therapy and monitoring requirements.**
- **ERIVEDGE can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.**
- **ERIVEDGE has not been studied in patients with severe impaired kidney function.**
- **ERIVEDGE is not recommended for use in patients with severe impaired liver function**
- **ERIVEDGE is only available under a controlled distribution program called the ERIVEDGE Pregnancy Prevention Program (EPPP).**
- **In children ERIVEDGE can cause bones to stop growing. This is called epiphyses premature fusion. It can happen even after stopping ERIVEDGE. This is a permanent effect.**

BEFORE you use ERIVEDGE, talk to your doctor or pharmacist if you:

- are pregnant, may be pregnant, or thinking about becoming pregnant
- are breastfeeding
- have liver problems
- have kidney problems

Contraception and pregnancy testing

Both males and females of childbearing potential need to take precautions so that a female is not exposed to ERIVEDGE during pregnancy.

Your doctor will counsel you and give you educational materials on the contraception requirements and risks of ERIVEDGE in pregnancy.

**For females:**

- Your healthcare provider will discuss with you whether you can become pregnant or not.

**For females who can become pregnant:**

- Your healthcare provider will talk to you about the possible risks of ERIVEDGE to your unborn baby if you become pregnant.
- ERIVEDGE may affect your ability to have children. Some females taking ERIVEDGE have stopped having periods. If this happens to you, it is not known if your periods will come back. Talk to your doctor if you wish to have children in the future.
- Pregnancy Testing:
  - Your healthcare provider will make sure to test you for pregnancy:
    - within 7 days before starting treatment to make sure you are not pregnant,
    - every month during treatment (including dose interruptions), and
    - for 24 months after you stop treatment.
  - Even if you stop menstruating, you will have to continue your regular monthly pregnancy tests during treatment.
- Contraception Requirements:
  - Your healthcare provider will talk to you about what contraceptive methods are right for you during this time.
  - Unless you commit to not having sexual intercourse, you must use 2 forms of acceptable contraceptive methods together, one of these must be a barrier method with a spermicide.
  - You must use appropriate contraception for at least 4 weeks before starting ERIVEDGE, during treatment (including dose interruptions) and for 24 months after you stop treatment.
  - Even if your periods have stopped, are irregular, or have abnormal menstrual bleeding, you must continue using the two recommended methods of contraception.
  - You must talk to your healthcare provider during the course of treatment and during the 24 months after you stopped treatment with ERIVEDGE before changing any contraceptive methods you have already agreed to use.
  - If you have previously chosen to not having sexual intercourse as a way to prevent pregnancy but you have changed your mind, you must talk to your doctor and commit to using 2 recommended methods of contraception together, as described above.
- Tell your healthcare provider right away if you:
  - become pregnant
  - think that you may be pregnant
  - have unprotected sexual intercourse
  - think your contraception has failed

**For females who can breastfeed:**

- Do not breastfeed during your treatment (including dose interruptions) and for 24 months after you stop taking ERIVEDGE. It is not known if ERIVEDGE can pass into your breast milk and harm your baby.

**For male patients:**

- You must advise your female sexual partners that you are taking ERIVEDGE and of the potential serious risks to an unborn baby if she becomes pregnant by you while you are on treatment (including dose interruptions) or for 2 months after you stop treatment.
- ERIVEDGE is present in semen.
- To protect your female partner from being exposed to ERIVEDGE, always use a condom with spermicide, even after a vasectomy, when you have sexual intercourse with a female partner. Do this during treatment (including dose interruptions) and for the 2 months after you stop treatment.
- You should not donate semen at any time during treatment (including dose interruptions) and for the 2 months after you stop treatment.
- Tell your healthcare provider right away if:
  - your female partner becomes pregnant
  - your female partner thinks she may be pregnant
  - you have unprotected sexual intercourse
  - you think your contraception has failed

<u>Exposure to ERIVEDGE during pregnancy</u>
ERIVEDGE must not be used during pregnancy. If you are female and are taking ERIVEDGE and think you may be pregnant, you must stop ERIVEDGE treatment and talk to your healthcare provider immediately.

If you are male and think that your female sexual partner may have been exposed to ERIVEDGE during pregnancy, talk to your healthcare provider immediately. Pregnant females who may have been exposed to ERIVEDGE during pregnancy should share information about their pregnancy when they are contacted.

<u>What you should avoid while taking ERIVEDGE</u>

- Do not donate blood or blood products while you are taking ERIVEDGE and for 24 months after you stop taking ERIVEDGE.
- Do not share your medicine with anyone even if they have the same symptoms as you.

## INTERACTIONS WITH THIS MEDICATION

Know the medicines you take and keep a list of your medicines with you. Tell your doctor or pharmacist if you are taking, have

recently taken or might take any other medicines. Include prescription and non-prescription medicines, vitamins, and herbal medicines.

## PROPER USE OF THIS MEDICATION

Take ERIVEDGE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 150 mg capsule each day.

- You can take ERIVEDGE with or without food.
- Swallow ERIVEDGE capsules whole.
- Do not open or crush the capsules.

Overdose:

If you think you have taken too much ERIVEDGE, contact your health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you miss a dose, do not take a double dose. Skip the missed dose and just take your next scheduled dose.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ERIVEDGE can cause side effects.

**Very common side effects**
*These side effects may affect more than 1 in 10 patients:*
- muscle spasm
- hair loss
- loss of taste (or a change in the way things taste)
- weight loss
- feeling tired
- feeling sick (nausea)
- diarrhea
- loss of monthly periods in women who can get pregnant
- loss of appetite
- constipation
- vomiting
- joint pain

**Common side effects**
- increases in liver enzymes (eg. feel tired or weak, abdominal pain, skin or eyes turn yellow)
- dehydration
- high and low blood pressure
- difficulty in swallowing
- back pain

Muscle spasm, loss of taste (or a change in the way things taste) and weight loss can continue to occur up to 12-months after you stop taking ERIVEDGE.

ERIVEDGE can cause abnormal blood test results. Your healthcare provider will do a blood test before you start taking ERIVEDGE and periodically during treatment and will interpret the results.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

The following serious side effects have occurred in clinical trials with ERIVEDGE.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPENED AND WHAT TO DO ABOUT THEM IF THEY HAPPEN TO YOU**

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|---|---|---|---|---|
| | | Only if severe | In all cases | |
| Common (occurring between 1 and 10 of every 100 patients in clinical trials) | Pneumonia | | ✓ | |
| | Heart failure (e.g. shortness of breath, fatigue, fainting, heart palpitations, swelling in legs, ankles, feet) | | ✓ | |
| | Broken hip | | ✓ | |
| | Bleeding in the digestive system (e.g. blood in your stool) | | ✓ | |
| | Skin infection (e.g. redness, warmth, swelling, and pain of skin) | | ✓ | |
| | Blood clots in the lungs (e.g. shortness of breath, chest pain) | | ✓ | |
| | Blood clots in the legs, which may cause pain in legs when walking or exercising | | ✓ | |
| | Bleeding | | ✓ | |
| | Scaly red patches, open sores with raised border, or warts | | ✓ | |
| | Fainting or sudden and temporary loss of consciousness | | ✓ | |

*This is not a complete list of side effects. For any unexpected effects while taking ERIVEDGE, contact your doctor or pharmacist.*

## HOW TO STORE IT

- **Keep ERIVEDGE capsules out of sight and reach of children.**
- ERIVEDGE should be stored at 15-30 ˚C. Store in the original package.
- Keep the bottle tightly closed in order to protect from moisture and heat.

It is recommended that ERIVEDGE not be disposed of in household waste or waste water. Please return any unused ERIVEDGE to a registered pharmacy.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:http://www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388

For more information on EPPP, please contact 1-888-748-8926 or visit www.erivedge.ca.

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