

MEDICATION GUIDE
ERIVEDGE® (EH-rih-vej)
(vismodegib)
capsule

What is the most important information I should know about ERIVEDGE?

ERIVEDGE can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

For females who can become pregnant:

- You should talk with your healthcare provider about the risks of ERIVEDGE to your unborn child.
- Your healthcare provider will do a pregnancy test within 7 days before you start taking ERIVEDGE.
- In order to avoid pregnancy, you should use birth control during treatment and for 24 months after your final dose of ERIVEDGE. Talk with your healthcare provider about what birth control method is right for you during this time.
- Talk to your healthcare provider right away if you have unprotected sex or if you think that your birth control has failed.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

For males:

- ERIVEDGE is present in semen. Do not donate semen while you are taking ERIVEDGE and for 3 months after your final dose.
- You should always use a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with ERIVEDGE and for 3 months after your final dose to protect your female partner from being exposed to ERIVEDGE.
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking ERIVEDGE.

Pregnancy Exposure Registry:

There is a Pregnancy Exposure Registry for females taking ERIVEDGE who become pregnant. The purpose of this registry is to monitor the health of you and your unborn baby. If you think that you or your female partner may have been exposed to ERIVEDGE during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with ERIVEDGE, you or your healthcare provider should report your pregnancy to Genentech at 1-888-835-2555.

What is ERIVEDGE?

ERIVEDGE is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body, or that has come back after surgery or that your healthcare provider decides cannot be treated with surgery or radiation.

It is not known if ERIVEDGE is safe and effective in children.

What should I tell my healthcare provider before taking ERIVEDGE?

Before taking ERIVEDGE, tell your healthcare provider if you:

- **are pregnant or plan to become pregnant.** See “What is the most important information I should know about ERIVEDGE?”
- **are breastfeeding or plan to breastfeed.** It is not known if ERIVEDGE passes into your breast milk. You should not breastfeed during treatment and for 24 months after your final dose of ERIVEDGE. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take ERIVEDGE?

- Take ERIVEDGE exactly as your healthcare provider tells you.
- You can take ERIVEDGE with or without food.
- Swallow ERIVEDGE capsules whole. **Do not open or crush the capsules.**
- Take ERIVEDGE 1 time each day.
- If you miss a dose, skip the missed dose. Just take your next scheduled dose.

What should I avoid while taking ERIVEDGE?

- **Do not** donate blood or blood products while you are taking ERIVEDGE and for 24 months after your final dose.

- **For Males: Do not** donate semen while you are taking ERIVEDGE and for 3 months after your final dose.

What are the possible side effects of ERIVEDGE?

ERIVEDGE can cause serious side effects, including:

- See “**What is the most important information I should know about ERIVEDGE?**”
- **Bone growth problems.** Bone growth problems have happened in children who have been exposed to ERIVEDGE. These problems may continue even after stopping treatment with ERIVEDGE.

The most common side effects of ERIVEDGE are:

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| • muscle spasms | • nausea |
| • hair loss | • diarrhea |
| • change in how things taste or loss of taste | • decreased appetite |
| • weight loss | • constipation |
| • tiredness | • joint pain |
| | • vomiting |

ERIVEDGE can cause absence of menstrual periods (amenorrhea) in females who are able to become pregnant. It is not known if amenorrhea is permanent. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of ERIVEDGE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech, Inc. at 1-888-835-2555.

How should I store ERIVEDGE?

- Store ERIVEDGE at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect ERIVEDGE from moisture.

Keep ERIVEDGE and all medicines out of the reach of children.

General information about the safe and effective use of ERIVEDGE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ERIVEDGE for a condition for which it was not prescribed. Do not give ERIVEDGE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ERIVEDGE that is written for health professionals.

What are the ingredients in ERIVEDGE?

Active ingredient: vismodegib

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium lauryl sulfate, povidone, sodium starch glycolate, talc, magnesium stearate (non-bovine). The capsule shell contains gelatin, titanium dioxide, red iron oxide, and black iron oxide. The black printing ink contains shellac and black iron oxide.

Manufactured by: Patheon, Inc. Mississauga, Canada

Distributed by: Genentech USA, Inc. A Member of the Roche Group 1 DNA Way South San Francisco, CA 94080-4990

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For more information, call 1-855-737-4833 or go to www.erivedge.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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