

Erivedge[®]▼ Pregnancy Prevention Programme (vismodegib)

*Important information for men and women
taking Erivedge about pregnancy prevention
and contraception*

- **Erivedge may cause severe birth defects.**
- **It may lead to the death of a baby before it is born or shortly after being born.**
- **You or your partner must not become pregnant while taking this medicine.**
- **You must follow the contraceptive advice described in this brochure.**

This brochure gives you a summary of important safety information and advice about taking Erivedge. This brochure does not replace the advice given to you by a healthcare professional (doctor, pharmacist or nurse). Read it carefully before you start taking Erivedge and keep it in case you need to read it again.

Please also read the Patient Information Leaflet inside each carton of Erivedge capsules for important information about taking this medicine.

If there is anything that you do not understand, or if you have any more questions, please talk to your healthcare professional.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 6 for how to report side effects.

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Read the specific instructions given to you by your doctor, particularly on the effects of Erivedge on unborn babies.

1. What is Erivedge and how does it work?

Erivedge is an anti-cancer medicine containing the active substance vismodegib. It is used to treat adults with a type of skin cancer called basal cell carcinoma.

It is used when the cancer:

- has spread to other parts of the body and is causing noticeable symptoms (called symptomatic “metastatic” basal cell carcinoma)
- has spread into areas nearby (called “locally advanced” basal cell carcinoma) and your doctor decides that treatment with surgery or radiation is inappropriate

Basal cell carcinoma develops when DNA in normal skin cells becomes damaged and the body cannot repair the damage. This damage can change how certain proteins in these cells work and the damaged cells become cancerous and begin to grow and divide.

Erivedge is an anti-cancer medicine that works by controlling one of the key proteins involved in basal cell carcinoma. This may slow or stop the cancer cells from growing, or may kill them. As a result, your skin cancer may shrink.

2. Who cannot take Erivedge?

Some people cannot take Erivedge. Do not take this medicine if any of the following apply to you. If you are not sure, talk to your doctor or pharmacist.

Do not take Erivedge if you:

- are **pregnant**, think you may be pregnant, or are planning to become pregnant during treatment or for 24 months after your final dose
- are **breast-feeding** or plan to breast-feed during the course of treatment or during the 24 months after your final dose
- are a woman who can become pregnant and you are **not using** recommended birth control (contraception, see section 5.1) or you do not refrain from sexual intercourse during treatment and for 24 months after the final dose
- have an **allergic** reaction to this medicine or any of the ingredients
- if you are also taking St John's Wort (*Hypericum perforatum*) a herbal medicine used for depression

3. Before you start taking Erivedge

- If you are a woman who could become pregnant, you must have a pregnancy test performed by a healthcare professional within 7 days of starting your treatment with Erivedge.
- As a patient you must review and sign the Erivedge Verification of Counselling Form with your prescriber.

4. During and after Erivedge treatment

Erivedge may harm a child before or after it is born.

- Do not become pregnant during treatment and for 24 months after your final dose, a monthly pregnancy test is recommended during treatment.
- Do not breast-feed during treatment and for 24 months after your final dose.
- Do not donate blood during treatment and for 24 months after your last dose.
- Keep Erivedge out of the sight and reach of children.
- Use recommended contraception as described in this brochure.
- Do not donate semen during treatment and for 2 months after your final dose.
- Never give this medicine to another person.
- Return the unused capsules to your pharmacist or doctor at the end of the treatment.

5. Pregnancy and Erivedge

Animal studies with Erivedge show severe deformities such as missing and/or fused fingers and toes, head and face abnormality, and retardations.

5.1. If you are a woman taking Erivedge who could become pregnant

Erivedge may cause severe deformities during development of an unborn child if you become pregnant during treatment and for 24 months after your final dose.

- If you are pregnant, you must not start taking Erivedge.
- You must have a pregnancy test performed by a healthcare professional to make sure you are not pregnant within 7 days before you start taking Erivedge.
- You must take a pregnancy test every month during treatment.
- If you are thinking about getting pregnant, talk to your healthcare professional about it.
- You must not become pregnant while you are taking Erivedge and for 24 months after your final dose.
- It is very important that you use **2** recommended forms of contraception from the table on page 6, one of which must be a barrier method (one barrier method **and** one highly effective form of contraception).
- You must use contraception during Erivedge treatment and for 24 months after your final dose, unless you commit to not having sex at any time (complete abstinence).
- If your periods stop during the course of treatment, you must still use recommended contraception during treatment and for 24 months after discontinuation of Erivedge.
- If your periods stop prior to the start of treatment with Erivedge as a result of previous anti-cancer medication, you must still use recommended contraception during treatment and for 24 months after discontinuation of Erivedge.
- Talk to your doctor about the best contraceptive methods for you.
- You must stop Erivedge and immediately inform your healthcare professional if you miss a menstrual period or you suspect you are pregnant.

Recommended forms of contraception

You must use 2 forms of contraception.

Use 1 form of contraception from **each** of the columns below.

| Barrier methods | | Highly effective forms of contraception |
|---|------------|--|
| <ul style="list-style-type: none">• male condom with spermicide OR <ul style="list-style-type: none">• diaphragm with spermicide | AND | <ul style="list-style-type: none">• hormonal depot injection OR• intrauterine device (“the coil” or IUD) OR• Tubal sterilisation OR• Vasectomy |

Talk to your healthcare professional if you are not sure which forms of contraception to use, or if you need more information.

5.2. If you are a man taking Erivedge

- The active ingredient in this medicine can pass into semen and may expose your female sexual partner to the drug. To avoid potential exposure during pregnancy, you must always use a condom (with spermicide, if available) even after a vasectomy, when you have sex with a woman during treatment and for 2 months after your final dose. It is also important your female partner is using contraception to avoid pregnancy.
- You should not donate semen during treatment and for 2 months after the final dose.

Talk to your healthcare professional if your female partner suspects that she is pregnant while you are taking Erivedge and for 2 months after your final dose.

5.3. If you suspect a pregnancy

You must talk to your healthcare professional immediately if you or your sexual partner misses a period, have unusual menstrual bleeding, suspect a pregnancy, or are pregnant.

- *Female patients:* talk to your doctor and stop taking Erivedge immediately if you suspect a pregnancy while taking this medicine and for 24 months after your final dose.
- *Male patients:* talk to your doctor if your female partner suspects that she is pregnant while you are taking Erivedge and for 2 months after your final dose.

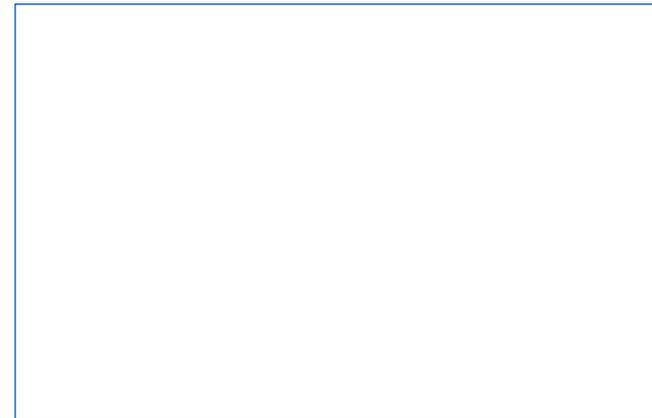
6. Common side effects of Erivedge

The Patient Information Leaflet has a full list of the known side effects of this medicine. It is important to know what side effects you may have during your treatment. Talk to your doctor if you experience any side effects while taking Erivedge.

6.1. Reporting of side effects

- ▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor pharmacist or nurse. You can also report side effects directly. Report forms can be found at www.medicinesauthority.gov.mt/adrportal and sent by email to postlicensing.medicinesauthority@gov.mt or posted to ADR Reporting, The Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D’Argens, Gżira G’ZR 1368, MALTA. Side effects should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

7. Patient reminder card





Marketing authorisation holder: Roche Registration Ltd, 6 Falcon Way, Shire Park,
Welwyn Garden City, AL7 1TW, United Kingdom. Erivedge is a registered trademark.

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