



Erivedge® Pregnancy Prevention Programme

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 contraception advice described in this leaflet

This brochure gives you a summary of important safety information and advice about taking Erivedge®. Read it carefully and keep it in case you need to read it again.

Please also read the Package Leaflet inside each carton for 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 doctor or pharmacist.

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1. Introduction

- 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 contraception advice described in this leaflet.

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

1.1 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 advanced basal cell carcinoma. It is used when the cancer:

- has spread to other parts of the body (called “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 become 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 down or stop the growth of the cancer cells, 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 below 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 could become pregnant and you are **not using** recommended birth control (contraception, see section 6.1) or not practicing total abstinence 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. Biological mechanisms and risk of birth defects

The Hedgehog pathway plays an essential role during development of the unborn baby. Animal studies with the active substance vismodegib show severe malformations such as missing and/or fused digits, head and face abnormality, and retardations.

4. Before you start taking Erivedge®

If you are a woman who could become pregnant, you must have a pregnancy test performed by a healthcare provider within a maximum of 7 days of starting your treatment with Erivedge®.

5. During and after Erivedge® treatment

Erivedge® may harm a child, before and after it is born.

- Do not become pregnant during treatment and for 24 months after your final dose, a monthly pregnancy test must be taken every month 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 anyone else.
- Return the unused capsules at the end of the treatment (*disposal will depend on local requirements*).

6. Pregnancy and Erivedge®

6.1 If you are a woman taking Erivedge® who could become pregnant:

Erivedge® may cause severe malformations 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 provider to make sure you are not pregnant within a maximum of 7 days before you start taking Erivedge® (day of pregnancy test = day 1).
- You must take a pregnancy test every month during treatment.
- If you are thinking about becoming pregnant, talk to your doctor or healthcare provider 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 below: one of which must be a barrier method (one barrier method **and** one highly effective form of contraception).

Recommended forms of contraception		
<p>You must use 2 forms of contraception.</p> <p>Use 1 form of contraception from each of the columns below.</p>		
Barrier methods		Highly effective forms of contraception
<ul style="list-style-type: none"> Male condom with spermicide OR Diaphragm with spermicide 	and	<ul style="list-style-type: none"> Hormonal depot injection OR Intrauterine device (IUD) OR Tubal sterilisation OR Vasectomy
<p>Talk to your doctor if you are not sure which forms of contraception to use, or if you need more information.</p>		

- You must use contraception (or complete abstinence) during Erivedge® treatment and for 24 months after your final dose, unless you commit to not having sex at any time (complete abstinence).
- If you have stopped menstruating during the course of treatment, you must still use recommended contraception during treatment and for 24 months after discontinuation of Erivedge®.
- If you have stopped menstruating 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 doctor or healthcare provider if you miss a menstrual period and you suspect you are pregnant.

6.2 If you are a man taking Erivedge®

- The active ingredient in this medicine can pass into semen and may expose your female sex partner. 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.
- You should not donate semen during treatment and for 2 months after the final dose.

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.

6.3 If you suspect a pregnancy

You must talk to your doctor or healthcare provider immediately if you or your sex partner miss 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.

7. Common side effects of Erivedge®

The Package 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®.

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RMPv14.1.0