



Erivedge[®] Pregnancy Prevention Programme:

**INFORMATION FOR PATIENTS
TAKING ERIVEDGE[®]**

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.

Introduction:

- ◆ **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.
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- ◆ 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 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 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.

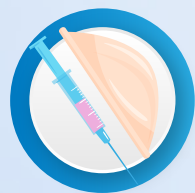
Do not take Erivedge® if you:



- ◆ **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.

Do not take Erivedge[®] if you:



- ◆ **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 (Erivedge) 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.**

5. During and after Erivedge[®] treatment



- ◆ **Do not donate blood during treatment** and for 24 months after your last dose.



- ◆ **Keep Erivedge[®] out of the sight and reach of children.**



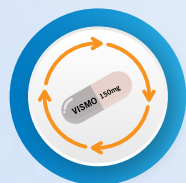
- ◆ **Use recommended contraception** as described in this brochure.



- ◆ **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:




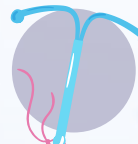


- ◆ **Erivedge[®] may cause severe malformations during development of an unborn child if you become pregnant during treatment** and for 24 months after your final dose.
 - ◆ **You must have a pregnancy test performed by a healthcare provider** to make sure you are not pregnant within a maximum of 7 days before you start taking Erivedge[®] (**day of pregnancy test = day 1**).
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- ◆ If you are pregnant, **you must not start taking Erivedge[®]**.
 - ◆ **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

- ◆ You must use 2 forms of contraception.
- ◆ Use 1 form of contraception from each of the columns below.

Barrier methods	AND	Highly effective forms of contraception
<ul style="list-style-type: none"> ◆  Male condom with spermicide ◆  Diaphragm with spermicide 	AND	<ul style="list-style-type: none"> ◆  Hormonal depot injection ◆  Intrauterine device (IUD) ◆  Tubal sterilisation ◆  Vasectomy

- ◆ **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.**

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:

- 1. you must always use a condom (with spermicide, if available)** even after a vasectomy, when you have sexual relations with a woman during treatment
- 2. You should not donate semen during treatment**

AND



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 affects you may have during your treatment. **Talk to your doctor if you experience any side effects while taking Erivedge®.**