FOR USE IN IRELAND

Erivedge® (vismodegib)

Pregnancy Prevention Programme

Patient Brochure – important information about pregnancy prevention and contraception for men and women taking Erivedge®

- 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 brochure

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.

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

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.medicines.ie before taking this medicine.

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1. Introduction

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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 (genetic material) 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 the course of treatment or for 24 months after your final dose.
- are **breastfeeding** or plan to breast-feed during the course of treatment or for 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.
- are also taking St John's wort *(Hypericum perforatum)* – a herbal medicine used for depression.
- are also taking rifampicin (used for bacterial infections), carbamazepine, phenytoin (used for epilepsy).

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 (fingers/toes), 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 your doctor or healthcare professional within a maximum of 7 days before starting your treatment with Erivedge®.
- You must review the Erivedge® (vismodegib) Patient Counselling Guidelines with your doctor or healthcare professional.
- If you are a woman who could become pregnant, your prescription for Erivedge® will be limited to 28 days supply. After this time, you will need to revisit your doctor to get a new prescription in order to continue Erivedge® treatment.

5. During and after Erivedge® treatment

Erivedge® may seriously 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 will be performed by your doctor or healthcare professional.
- 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 to your local pharmacy at the end of the treatment.

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 your doctor or healthcare professional within a maximum of 7 days before you start taking Erivedge® (day of pregnancy test = day 1) to make sure you are not pregnant.
- You must have a pregnancy test performed by your doctor or healthcare professional every month during treatment.
- If you are thinking about becoming pregnant, talk to your doctor or 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 **TWO** 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 **TWO** forms of contraception. Use **ONE** form of contraception from **EACH** of the columns below.		
Barrier methods	**and**	**Highly effective forms of contraception**
▪ Male condom with spermicide **OR** ▪ Diaphragm with spermicide		▪ Hormonal depot injection **OR** ▪ Intrauterine device (IUD) **OR** ▪ Tubal sterilisation **OR** ▪ Vasectomy
Talk to your doctor if you are not sure which forms of contraception to use, or if you need more information.		

- You must use contraception (or complete abstinence) without interruption, 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 professional if:
  - you miss a menstrual period.
  - you think your contraception has failed for any reason.
  - you stop using contraception.
  - you need to change contraception.
  - 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 your 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 professional 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 or healthcare professional i.e. nurse or pharmacist if you experience any side effects while taking Erivedge®.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Please report side effects to:
Post: The Drug Surveillance Centre, Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Or report to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

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