Erivedge® Pregnancy Prevention Programme

Version: 2

I. Health Care Provider Material
- **Healthcare Provider Reminder Card**
- **Patient Counselling Guideline**

II. Patient Educational Material
- **Patient Brochure**

1. HEALTHCARE PROVIDERS REMINDER CARD

Erivedge® Reminder for Healthcare Providers.

Contraindication to:
- Women who are pregnant or breastfeeding
- Women of childbearing potential who do not comply with the Erivedge® Pregnancy Prevention Programme

Female patients of childbearing potential must:
- Take monthly pregnancy test even if patient becomes amenorrhoeic.
- Always use recommended contraception while taking Erivedge® and for 24 months after their final dose.
- Not breast-feed during treatment and for 24 months after their final dose.

Male patients must:
- Use condoms (with spermicide if available) when having sex with a female partner while taking Erivedge® and for 2 months after their final dose.
- Not donate semen during treatment and for 2 months after the final dose of this medicine.

The patient must contact you urgently if a pregnancy is suspected in a female patient or in a female partner of a male patient.

You must:
- Assess pregnancy status, counsel the patient for teratogenicity risk, and refer the patient and female partner to a specialist.
- Report all confirmed pregnancies to Roche.

All patients must:
- Never give this medicine to another person.
- Return the unused capsules at the end of the treatment *(disposal will depend on local requirements).*
- Not donate blood during treatment and for 24 months after their final dose.

Prescriber's role in the Erivedge® pregnancy prevention programme

- Educate patients about the risks of teratogenicity associated with exposure to Erivedge® during pregnancy.
- Ensure that patients are capable of complying with the requirements for the safe use of Erivedge®.
- Ensure that patients who are women of childbearing potential have a negative medically supervised pregnancy test within a maximum of 7 days prior to initiating treatment (day of pregnancy test = day 1) and have monthly medically supervised pregnancy tests during treatment.

- Ensure that for patients who are women of childbearing potential, prescriptions of Erivedge® should be limited to 28 days of treatment and continuation of treatment requires a new prescription.
- Ensure that patients who are women of childbearing potential are able of complying with contraceptive measures during Erivedge® treatment and for 24 months after their final dose.
- Since Erivedge® is present in semen, every male patient must understand the risks to the unborn child and use condoms (with spermicide if available), even if he has had a vasectomy, during sex with female partners during treatment and for 2 months after final dose, to prevent exposure to Erivedge®.
- Provide your patient with the brochure "Erivedge® Pregnancy Prevention Programme: Information for patients taking Erivedge®", which contains information and advice about taking Erivedge®
- Report any pregnancies to Roche.
- Refer the patient to a specialist physician in the event of pregnancy.

Further information on Erivedge® side effects and pregnancy prevention can be found in the Erivedge® SmPC and Package Leaflet.

2. PATIENT COUNSELLING GUIDELINE

Erivedge® Patient Counselling Guideline
WARNING: EMBRYO-FOETAL DEATH AND SEVERE BIRTH DEFECTS Erivedge® may cause embryo-foetal death or severe birth defects when administered to a pregnant woman. Hedgehog pathway inhibitors such as Erivedge® have been demonstrated to be embryotoxic and/or teratogenic in multiple animal species and can cause severe malformations, including craniofacial anomalies, midline defects and limb defects. Erivedge® must not be used during pregnancy.
For All Patients
I Understand that:
• Erivedge® may cause serious birth defects and can cause the death of a unborn child.
• I must not give Erivedge® to another person. Erivedge® is only prescribed for me.
• I must keep Erivedge® out of the sight and reach of children.
• I must not donate blood while taking Erivedge® and for 24 months after the last dose.
• I must return the unused capsules at the end of the treatment.
For Women Who Could Become Pregnant
I Understand that:
• I must not take Erivedge® if I am pregnant or plan to become pregnant
• I must not become pregnant while taking Erivedge® and for 24 months after my final dose
• My healthcare provider talked with me about recommended forms of birth control
○ I must use 2 recommended forms of birth control at the same time while I am taking Erivedge® ○ Unless I commit to not having sexual intercourse at any time (abstinence)
• I must have a negative pregnancy test conducted by my healthcare provider within a maximum of 7 days (day of pregnancy test = day 1) before starting Erivedge® and each month during treatment

• I must talk to my healthcare provider immediately during treatment and for 24 months after my last dose: ○ If I become pregnant or think for any reason that I may be pregnant ○ If I miss my expected menstrual period ○ If I stop using birth control ○ If I need to change birth control during treatment
• In case of pregnancy during treatment with Erivedge®, I must stop treatment immediately • I must not breast-feed while I am taking Erivedge® and for 24 months after my last dose
• My healthcare provider will report any pregnancy to Roche, the maker of Erivedge®.
For Male Patients
I Understand That:
I must always use a condom when having sex with a woman while I take Erivedge® and for 2 months after my last dose, even if I have had a vasectomy.
I will tell my healthcare provider if my female sex partner becomes pregnant while I am taking Erivedge® or within 2 months after my last dose
I should not donate semen at any time during treatment and for 2 months after my final dose of this medicine
Report Pregnancy and Adverse Events To Roche at xxx-xxx-xxxx

II. Patient Brochure: "Erivedge® Pregnancy Prevention Programme: Information for Patients Taking Erivedge®"

BROCHURE COVER:

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