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 3 months after their final dose.
- Not donate semen during treatment and for 3 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 Drug Safety at (02) 2715-3111.

All patients must:
- Never give this medicine to another person.
- Local requirements should be followed for the disposal process of unused medicines.
- 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 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 3 months after final dose, to prevent exposure to Erivedge®.
- Provide your patient with the Patient Leaflet "Erivedge® Pregnancy Prevention Programme: Information for patients taking Erivedge®", which contains information and advice about taking Erivedge®
- Report any pregnancies to Roche Drug Safety at (02) 2715-3111.

• Refer the patient to a treating physician in the event of pregnancy.

Further information on Erivedge® side effects and pregnancy prevention can be found in the Erivedge® Package Insert and Patient 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 an unborn child.
o 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 follow the local requirements for disposal process of unused medicines.
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
o I must use 2 recommended forms of birth control at the same time while I am taking Erivedge® o 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: o If I become pregnant or think for any reason that I may be pregnant o If I miss my expected menstrual period o If I stop using birth control o 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 3 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 3 months after my last dose
• I should not donate semen at any time during treatment and for 3 months after my final dose of this medicine
Report Pregnancy and Adverse Events To Roche Drug Safety: (02) 2715-3111