Healthcare Provider Reminder Card

Roche Hong Kong Limited
22/F, FTLife Tower,
18 Sheung Yuet Road,
Kowloon Bay, Hong Kong
RMPv14.1.0

Erivedge®
vismodegib

Contraindication to:

- Hypersensitivity to the active substance or to any of the excipients.
- Women who are pregnant or breast-feeding.
- Women of childbearing potential who do not comply with the Erivedge® Pregnancy Prevention Programme.
- Co-administration of St John's wort (*Hypericum perforatum*).

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 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®” or Chinese version “Erivedge®懷孕預防計劃”, 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® Product Insert.

Roche Affiliate Safety Reporting Contact Information

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