## Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions (see details below).

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

**In the event of a suspected adverse event, please report it to:**
**Post:** The Drug Surveillance Centre,
Roche Products (Ireland) Limited,
3030 Lake Drive,
Citywest Business Campus,
Dublin 24, D24 KX6Y, Ireland.
**Telephone:** 00 353 (0)1 4690700
**Email:** ireland.drug_surveillance_centre@roche.com

**Alternatively, suspected adverse reactions or medication errors may be reported using the Medicines Authority ADR reporting form,** which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:
**Post:** Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority,
Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.
**Email:** postlicensing.medicinesauthority@gov.mt

## Further Information

**For electronic copies of this risk minimisation material,** refer to the Malta Medicines Authority website [http:/www.medicinesauthority.gov.mt/rmm] and download the required material.
**Alternatively if you would like hard copies,** please contact Roche Products (Ireland) Limited, 3030 Lake Drive, Citywest Business Campus, Dublin 24, D24 KX6Y, Ireland by mail, telephone [00 353 (0)1 4690700] or email [ireland.drug_surveillance_centre@roche.com].

**For further information about this medicine,** please contact Medical Information at Roche Products (Ireland) Limited by telephone [00 353 (0)1 4690700] or email [Ireland.druginfo@roche.com].

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**FOR USE IN MALTA**

# Erivedge® (vismodegib)
# Healthcare Professional Reminder Card

**This is additional risk minimisation material and is provided by Roche Products (Ireland) Limited as a condition of the Erivedge® marketing authorisation.**

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.ema.europa.eu before prescribing this medicine.

**Erivedge® Reminder for Healthcare Providers:**

## Contraindication to:

- Women who are pregnant or breast-feeding.
- Women of childbearing potential who do not comply with the Erivedge® Pregnancy Prevention Programme.

## Female patients of childbearing potential must:

- take monthly pregnancy tests during treatment even if the 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.
- only be prescribed Erivedge® for a maximum treatment period of 28 days. Continuation of treatment requires a new prescription.

## Male patients must:

- use condoms (with spermicide if available) even after a vasectomy 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 immediately 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 for counselling in the event of pregnancy to a specialist.
- report all confirmed pregnancies to Roche (see overleaf for contact details for reporting).

## All patients must be reminded to:

- never give this medicine to another person.
- return all unused capsules at the end of the treatment to their local pharmacy.
- 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 supply and continuation of treatment required 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.
- As Erivedge® is present in semen, every male patient must understand the risks to the unborn child and use a condom (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® Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) available online at www.ema.europa.eu.