

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).



▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Reporting forms and information can be found at

www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

Erivedge[®] ▼ (vismodegib)

Healthcare professional reminder card

Marketing authorisation holder: Roche Registration Ltd, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. Erivedge is a registered trademark.

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This educational material is provided by Roche Products Limited and mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

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

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 female patient to a specialist obstetrician or in the case of a female partner of a male patient recommend urgent specialist referral
- report all confirmed pregnancies to Roche

ALL PATIENTS must:

- never give this medicine to another person
- return all unused capsules at the end of the treatment
- not donate blood during treatment and for 24 months after their final dose

Complete the survey for all new patients in the HCP web portal (www.erivedge-ppp.com.mt)

Login: hcportal

Password: erivedge