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. 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.

Any suspected adverse reaction should be reported. Report forms can be found at **www.medicinesauthority.gov.mt/adrportal** and sent by email to postlicensing.medicinesauthority@gov.mt or posted to ADR Reporting, The Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA. 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.

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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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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: hcpportal
Password: erivedge