FOR USE IN IRELAND

Erivedge® (vismodegib)
Patient Counselling Guidelines

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

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.	**INITIALS**
For All Patients	
Check that the patient understands that:	
▪ Erivedge® may cause serious birth defects and can cause the death of an unborn child	
▪ Erivedge® must not be given to another person. Erivedge® is only prescribed for the patient's use	
▪ Erivedge® must be kept out of the sight and reach of children	
▪ The patient must not donate blood while taking Erivedge® and for 24 months after the last dose	
▪ The unused capsules must be returned to the patient's pharmacy at the end of their treatment	
For Women Who Could Become Pregnant	
Check that the patient understands that:	
▪ She must not take Erivedge® if she is pregnant or plans to become pregnant	
▪ She must not become pregnant while taking Erivedge® and for 24 months after her final dose	
▪ Her doctor or healthcare professional talked with the patient about recommended forms of birth control	
– She must use 2 recommended forms of birth control at the same time while she is taking Erivedge®	
– Unless she commits to not having sexual intercourse at any time (abstinence)	
▪ She must have a negative pregnancy test conducted by her doctor or healthcare professional within a maximum of 7 days (day of pregnancy test = day 1) before starting Erivedge® and each month during treatment	

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

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▪ She must talk to her doctor or healthcare professional immediately during treatment and for 24 months after her last dose:	
– If she becomes pregnant or thinks for any reason that she may be pregnant	
– If she misses her expected menstrual period	
– If she stops using birth control	
– If she needs to change birth control during treatment	
– If she thinks her birth control has failed for any reason	
▪ In case of pregnancy during treatment with Erivedge®, she must stop treatment immediately	
▪ She must not breast-feed while taking Erivedge® and for 24 months after her last dose	
▪ The patient's doctor or healthcare professional will report any pregnancy to Roche (the maker of Erivedge®)	
For Male Patients	
Check that the patient understands that:	
▪ A condom must always be used (with spermicide, if available) when having sex with a woman while he takes Erivedge® and for 2 months after his final dose, even if the patient has had a vasectomy	
▪ He will tell his doctor or healthcare professional if his female sex partner becomes pregnant while he is taking Erivedge® or within 2 months after his last dose	
▪ Semen should not be donated at any time during treatment and for 2 months after his final dose of this medicine	

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 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,
3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Erivedge' or 'vismodegib' in the search box and click on 'EdM' next to any of the medicines that appear). **Alternatively if you would like hard copies**, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone (01 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 (01 4690700) or email (Ireland.druginfo@roche.com).

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