Erivedge®▼(vismodegib) Verification of Counselling Form	Initials
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.	
For All Patients	
I understand that:	
• Erivedge may cause serious birth defects and can cause the death of an unborn child	
• I must not share Erivedge with anyone. Erivedge is only prescribed for me	
• I must keep Erivedge out of the sight and reach of children	
• I must not donate blood while taking Erivedge and for 24 months after the last dose	
• I must return the unused capsules to my pharmacist or healthcare professional at the end of the treatment	
For Women Who Could Become Pregnant	
I understand that:	
• I must not take Erivedge if I am pregnant or plan to become pregnant	
• I must not become pregnant while taking Erivedge and for 24 months after my final dose	
• My healthcare professional talked with me about recommended forms of birth control: – Whilst I am taking Erivedge and for 24 months after my final dose, I must use 2 recommended forms of birth control at the same time unless I commit to not having sexual intercourse (abstinence)	
• I must have a negative pregnancy test conducted by my healthcare professional within 7 days before starting Erivedge and each month during treatment	
• I must talk to my healthcare professional immediately during treatment and for 24 months after my last dose: – If I become pregnant or think for any reason that I may be pregnant – If I miss my expected menstrual period – If I stop using birth control – If I need to change my birth control during treatment	
• In case of pregnancy during treatment with Erivedge, I must stop treatment immediately	
• I must not breast-feed while I am taking Erivedge and for 24 months after my last dose	
• My healthcare professional will report any pregnancy to Roche, the maker of Erivedge	
For Male Patients	
I understand that:	
• I must always use a condom when having sex with a woman while I take Erivedge and for 2 months after my last dose, even if I have had a vasectomy. It is also important that my female partner uses contraception to avoid pregnancy	
• I will tell my healthcare professional if my female sexual partner becomes pregnant while I am taking Erivedge or within 2 months after my last dose	
• I should not donate semen at any time during treatment and for 2 months after my final dose of this medicine	
Report Pregnancy and Adverse Events to Roche on +44 (0)1707 367554	

Patient gender *(circle one):*	**Age:**	**Woman of childbearing potential** *(circle one):*
Male Female	_____ years	Yes No

Pre-treatment pregnancy test results *(circle one):*	**Date of the pre-treatment pregnancy test:**
Positive Negative	_____/_____/_____

Patient Confirmation

My doctor has reviewed with me the risks to an unborn baby or infant if they are exposed to Erivedge during pregnancy or breast-feeding. He/she has answered any questions I may have about these risks, and how to prevent them.

Patient Name (please print): _____

Patient Signature: _____

Date: _____

Prescriber Confirmation

I have explained to the patient named _____ (or the parent or guardian if the patient is mentally challenged) the risks of the treatment associated with Erivedge, including the risk of exposure to the unborn baby and/or infant during pregnancy and breast-feeding. I have asked the patient (or the parent or guardian if the patient is mentally challenged) if she/he has any questions regarding treatment and have answered those questions to the best of my ability.

Prescriber Name (please print): _____

Prescriber Signature: _____

Date: _____

PLEASE RETAIN THE ORIGINAL SIGNED DOCUMENT AND PROVIDE A COPY TO THE PATIENT

Prescribers must confirm completion of this Verification of Counselling Form for all new patients taking Erivedge via the healthcare professional web portal **www.erivedge-ppp.com.mt**

▼ 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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