

# Lenalidomide Pregnancy Prevention Programme (PPP)

## Woman of Non-Childbearing Potential Risk Awareness Form

**IRELAND**



**Patient: please read thoroughly and initial the adjacent box if you agree with the statement**

I understand that severe birth defects are expected to occur with the use of lenalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking lenalidomide.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Guide and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	Patient initials
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each lenalidomide prescription, and that I must provide this to my pharmacy.	Patient initials
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure lenalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of lenalidomide.	Patient initials

**Patient Confirmation**

I confirm that I understand and will comply with the requirements of the lenalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with lenalidomide.

Your personal data is used solely for the purpose of entering you into the lenalidomide Pregnancy Prevention Programme and is processed by the marketing authorisation holder (MAH) of the lenalidomide product you receive, its third-party service providers and any affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the lenalidomide product you receive.

Your pharmacist can confirm the details of the MAH for the lenalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g. on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

Patient Signature:		Date:	DD	MM	YYYY
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**Statement of the interpreter (where appropriate)**

I have interpreted the information above to the patient/parent/carer to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to lenalidomide.

Signed:		Name: (print)		Date:	DD	MM	YYYY
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