Introduction

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their lenalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

It is mandatory that males receive counselling and education to be made aware of the risks of lenalidomide.

The aim of the Treatment Initiation Form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of lenalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure.

Warning: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name	
Patient Last Name	

Date of Birth	DD	MM	YYYY	Counselling Date	DD	MM	YYYY

Pregnancy Prevention

The Patient Confirms that:	
They will use a condom during intercourse with a woman of childbearing potential	Tick
Their female partner is using an effective method of contraception	Tick
Their female partner is of non-childbearing potential	Tick
They are committed to complete and absolute abstinence	Tick

Statement of the interpreter (Where Appropriate)

I have interpreted the information above to the patient 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

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with lenalidomide especially the risks to women of childbearing potential. I will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber First Name	
Prescriber Last Name	

Prescriber Signature		Date	DD	MM	YYYY

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 passes into human semen. If my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions and for at least 7 days after I stop lenalidomide even if I have had a vasectomy.	Patient Initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient Initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE	Patient Initials
I have read and understand the lenalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of lenalidomide.	Patient Initials
I understand that I cannot donate blood, semen or sperm while taking lenalidomide (including dose interruptions) or 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 effective contraceptive methods that my female partner can use.	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 send or may provide me with a completed 'Prescription Authorisation Form' with each lenalidomide prescription for the pharmacy.	Patient Initials
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure lenalidomide is dispensed safely. This information may be used by the Marketing Authorisation Holder and the distributor for 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 worldwide 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

Important Safety Information:

This is risk minimisation material and is provided as a collaborative project between Accord Healthcare Ireland Ltd., Clonmel Healthcare Ltd., Mylan Ireland Limited and Teva Pharmaceuticals Ireland. For further information, please refer to the Summary of Product Characteristics (SmPC) for the respective medicinal product from the relevant Marketing Authorisation Holder available at www.hpra.ie