Lenalidomide Treatment Initiation Form

For All Patients (Female of childbearing potential, Female of non-childbearing potential and Male)

IRELAND

This Treatment Initiation Form must be completed for each patient prior to the initiation of their lenalidomide treatment.

It is mandatory that all patients receive counselling and education to be made aware of the risks of lenalidomide. In particular, lenalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

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.

Patients:
Women of childbearing potential: Complete Part A and Part B ***Men: Complete Part A and Part C***

Prescribers:
For female patients of childbearing potential complete Part D ***For male patients complete Part E***

The form should be retained with the patient's medical records, and a copy provided to the patient.

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 and Last Name	
Date of Birth	DD MM YYYY

Prescriber details

Prescriber First and Last Name	
Counselling Date	DD MM YYYY

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

PART A (all Patients)	
• I understand that lenalidomide is expected to be harmful to an unborn baby and that severe birth defects may 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.	TICK
• I have read the lenalidomide patient booklet and understand the contents.	TICK
• I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	TICK
• I understand that I must return any unused capsules to my pharmacy at the end of my treatment.	TICK
• I understand that I cannot donate blood during treatment, including dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide.	TICK
• 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.	TICK
• 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 and the distributor for the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of Lenalidomide*.	TICK

Patient signature:	**Date:** DD MM YYYY

PART B (only for Female Patients of Childbearing Potential)	
• I understand that I must not take lenalidomide if I am pregnant or plan to become pregnant.	TICK
• I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	TICK
• I understand that if I need to change or stop my method of contraception, I will discuss this first with the presciber prescribing my contraception and the presciber prescribing my lenalidomide. I understand that I must comply with the advice on contraception even if monthly menstrual bleedings are not present during therapy.	TICK
• I understand that that even if I have amenorrhoea I must comply with advice on contraception.	TICK
• I understand that before starting lenalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	TICK
• I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant or suspect I am pregnant while taking this drug or within 4 weeks of treatment end, if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	TICK
Patient signature:	**Date:** DD MM YYYY

PART C (only for Male Patients)	
• I understand that lenalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she does not 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.	TICK
• I understand that if I think my partner may be pregnant whilst I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide I should inform my prescriber immediately and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	TICK
• I understand that I cannot donate semen or sperm while taking lenalidomide, during dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about effective contraceptive methods that my female partner can use.	TICK
Patient signature:	**Date:** DD MM YYYY

Patient confirmation

I confirm that the prescriber explained the risk of teratogenicity and other adverse effects associated with the use of lenalidomide. 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.

Patient signature:	**Date**: DD MM YYYY

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent 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.

Interpreter name and signature:	**Date:** DD MM YYYY

*****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.

Prescriber: For Female Patients of Childbearing Potential (Part D) and Males (Part E)

PART D (Confirm for Female Patients of Childbearing Potential)

Contraceptive referral for Female Patients of Childbearing Potential

- Contraceptive referral required: YES/NO
- Date Contraceptive referral made: DD MM YYYY
- Date Contraceptive consultation conducted on: DD MM YYYY

Pregnancy Prevention for Female Patients of Childbearing Potential

The patient has been established on one of the following

• Implant	TICK
• Levonorgesterel-releasing intrauterine system (IUS)	TICK
• Medroxyprogesterone acetate depot	TICK
• Tubal sterilisation	TICK
• Sexual intercourse with a vasectomised male partner only, vasectomy must be confirmed by two negative semen analyses	TICK
• Ovulation inhibitory progesterone-only pills (e.g. desogestrel)	TICK
• Committed to complete and absolute abstinence	TICK

Pregnancy test

Date of last negative pregnancy test: DD MM YYYY

Lenalidomide treatment cannot start until the patient has been established on at least one effective method of contraception for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

Prescriber signature: **Date**: DD MM YYYY

PART E (Confirm for Male Patients)

Pregnancy Prevention for Male Patients

The patient confirms that:

• They will use a condom during intercourse with a female of childbearing potential	TICK
• Their female partner is using an effective contraceptive method	TICK
• Their female partner is of non-childbearing potential	TICK
• They are committed to complete and absolute abstinence	TICK

Prescriber signature:	**Date:** DD MM YYYY

Prescribers Confirmation

I confirm that:

- 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 have fully explained to the patient named above the importance of compliance with the requirements of the lenalidomide Pregnancy Prevention Programme.
- I will comply with all my obligations and responsibilities as the prescriber of lenalidomide.

Prescriber signature:	**Date**: DD MM YYYY