Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of lenalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence lenalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female patient of childbearing potential prior to the initiation of their lenalidomide treatment.
The purpose of the Risk Awareness 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 drug reactions associated with the use of lenalidomide.

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

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding 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

Did you inform your patient:

1)	Of the expected teratogenic risk to the unborn child and the need to avoid foetal exposure	Tick
2)	That if she is pregnant or plans to be, she must not take lenalidomide	Tick
3)	Of the need to avoid lenalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	Tick
4)	That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking lenalidomide b) the prescriber prescribing lenalidomide that she has stopped or changed her method of contraception	Tick
5)	Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment	Tick
6)	Of the need to stop lenalidomide immediately upon suspicion of pregnancy	Tick
7)	Of the need to contact their prescriber immediately upon suspicion of pregnancy	Tick
8)	To not share the medicinal product with any other person	Tick
9)	That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide	Tick

10) That they should return the unused capsules to the pharmacist at the end of treatment	Tick
11) That even if patient has amenorrhoea they must comply with advice on contraception.	Tick
12) Of the hazards and necessary precautions associated with use of lenalidomide.	Tick
13) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with lenalidomide	Tick
14) About which are effective contraceptive methods that she can use	Tick

Can you confirm your patient:

1) Was referred to a contraceptive consultant, if required?	Tick
2) Is capable of complying with contraceptive measures?	Tick
3) Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	Tick
4) Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	Tick

Contraceptive Referral

Contraceptive Referral Made		Yes	No
Contraceptive Consultation Conducted on	DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-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 (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND THE PREGNANCY TEST IS NEGATIVE.

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 I must not take lenalidomide if I am pregnant or plan to become pregnant.	Patient Initials
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 the 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.	Patient Initials
I understand that if I need to change or stop my method of contraception I will discuss this first with the Healthcare professional of my contraception and the prescriber prescribing my lenalidomide.	Patient Initials
I understand that before starting the 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.	Patient Initials
I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	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 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 understand that even if I have amenorrhoea I must comply with advice on contraception.	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.

Patients Signature		Date	DD	MM	YYYY

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

Important Safety Information:

This is risk minimisation material and is provided as a collaborative project between Accord Healthcare Ireland Ltd., Clonmel Healthcare Ltd. Rowex ltd 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

Version 4.0

Approval Date: February 2026