Lenalidomide
Pregnancy Prevention Programme (PPP)

Women of Non-Childbearing Potential
Risk Awareness Form

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

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 woman of non-childbearing potential prior to the initiation of their Lenalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

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 effects associated with the use of lenalidomide. It is mandatory that woman of non-childbearing potential receive counselling and education to be made aware of the risks of lenalidomide.

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

	WNCBP
1 To not share the medicinal product with any other person	
2 That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide	
3 That they should return the unused capsules to the pharmacist at the end of treatment	

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 my obligations and responsibilities as the prescribing physician 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 have read the lenalidomide Patient Booklet 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 lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I know that I cannot donate blood while taking Lenalidomide (including dose interruptions) and for a 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

Patient Confirmation

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

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF)) will be processed by Accord-UK Ltd as the Marketing Authorisation Holder of Lenalidomide Accord for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or Accord. For further information on how to exercise your rights and how we process your data, visit our privacy policy available on our website www.accord-healthcare.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

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.

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

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