

# Lenalidomide Pregnancy Prevention Programme (PPP)

## **Woman of Childbearing Potential Treatment Initiation Form**

UK



## Pregnancy Test

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

## 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 physician prescribing my contraception and the physician 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 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 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 used 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

**Patient Confirmation**

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

Personal data is used solely for the purpose of entering you into the Pregnancy Prevention Programme and is processed by Dr. Reddy's Laboratories, as marketing authorisation holder of pharmaceutical products and its worldwide Affiliates, to the extent and 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 us at [XXX@XXX.com](mailto:XXX@XXX.com)

Patient Signature:		Date:	<i>DD</i>	<i>MM</i>	<i>YYYY</i>
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**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:	<i>DD</i>	<i>MM</i>	<i>YYYY</i>
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