Lenalidomide
PREGNANCY PREVENTION PROGRAM
Women of Non-Childbearing Potential Treatment Initiation Form

Australia

Cipla

Approved by TGA: November 2022

Introduction

It is mandatory that woman of non-childbearing potential 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.

This treatment initiation form must be completed for each woman of non-childbearing potential prior to the initiation of their lenalidomide treatment. The form should be retained with their 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 malformations in monkeys 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 Program 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:	Counselling Date:

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:

Patient/authorised representative: please read carefully and 'tick' inside the box, next to the questions that apply to you, provided 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.	
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	
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.	
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment.	
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during the treatment with lenalidomide.	

Patient Confirmation
I confirm that I understand and will comply with the requirements of lenalidomide Pregnancy Prevention Program, and I agree that my prescriber can initiate my treatment with lenalidomide. I consent to the use of my personal data collected pursuant to the pregnancy prevention program for the purposes of administering any prevailing guidance on the use of lenalidomide.
Patient Signature: Date: