Lenalidomide
PREGNANCY PREVENTION PROGRAMME (PPP)
Male Treatment Initiation Form

Australia

Cipla

Approved by TGA: November 2022

Introduction

The aim of this 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 does not constitute a contract and does not absolve potential male patients from his responsibilities with regard to the safe use of the product and prevention of foetal exposure. This Treatment initiation form must be completed for each male patient 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:

Pregnancy Prevention	Tick ✓or Not Applicable
The patient confirms that:	
They will use condoms during intercourse with a woman of childbearing potential	
Their female partner is using an effective method of pregnancy prevention	
Their female partner is of non-childbearing potential	
They are committed to complete and absolute abstinence	

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 may occur with the use of lenalidomide. I have been warned by my prescriber that any unborn baby may have high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking lenalidomide	
I understand that lenalidomide passes into human semen, if my partner is pregnant or able to become pregnant, and she doesn't use effective contraception, I must use condoms throughout duration of my treatment, during using dose interruption and for at least 7 days after I stop lenalidomide even if I have had a successful vasectomy.	
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE	
I have read the lenalidomide Patient Information Brochure and understand the contents, including the information about other possible health problems (side effects) from Lenalidomide	
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialized or experienced in teratology for evaluation and advice.	
I understand that I cannot donate blood while taking lenalidomide (including dose interruption) or for at least 7 days after discontinuation of lenalidomide treatment. Note: In Australia patients with multiple myeloma are permanently excluded from donating blood.	
I know that I cannot donate semen or sperm while taking lenalidomide, during dose interruptions and for at least 7 days after discontinuation of lenalidomide treatment.	
I have been informed about which are effective contraceptive methods that my female partner can use.	
I understand that I must return any unused lenalidomide capsules to my pharmacy at the end of my treatment	

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 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: