Lenalidomide
PREGNANCY PREVENTION PROGRAM
Women of Childbearing Potential Treatment Initiation Form

Australia

Cipla

Approved by TGA: November 2022

Introduction

This treatment initiation form must be completed for each woman of 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.

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

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.

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:

Contraceptive Referral
Contraceptive referral required: Contraceptive referral made: Contraceptive consultation conducted on:

Pregnancy Prevention	**Tick ✓or Not Applicable**
The patient has been established on one of the following for at least 4 weeks	
Contraceptive implant	
Levonorgestrel-releasing intrauterine system (IUS)	
Medroxyprogesterone acetate depot	
Tubal sterilization	
Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by two negative semen analyses	
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	
Committed to complete and absolute abstinence (confirmed on a monthly basis)	

Pregnancy Test	
Date of last negative pregnancy test	

Lenalidomide treatment cannot start until the patient has been established on effective method of contraception for at least 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:

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 I must not take lenalidomide If I am pregnant or plan to become pregnant	
I understand that I must use at least one effective method of contraceptive without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even if in case of dose interruption, and 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.	
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.	
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 sterilization, I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after end of treatment.	
I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant while taking the drug, or if I miss my menstrual period, experience unusual menstrual bleeding, or think, FOR ANY REASON, that I may be pregnant.	
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 know that I cannot donate blood while taking lenalidomide (including dose interruption) and for at least 7 days after stopping treatment.	
I understand that even if I have amenorrhea I must comply with advice on contraception.	
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: