Revlimid® (lenalidomide) Pregnancy Prevention Programme

Woman Not of Childbearing Potential

Treatment Initiation Form

Introduction

This Treatment Initiation Form must be completed for each woman not of childbearing potential prior to the initiation of their Revlimid® (lenalidomide) treatment. The form should be retained with their medical records, and a copy provided to the patient.

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 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 fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If lenalidomide is taken during pregnancy it may cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name	
Patient Last Name	
Date of Birth, *Age or Age Group*	
Counselling Date	

Checklist for Counselling

This checklist is to assist you with counselling a patient before they commence Revlimid® (lenalidomide) treatment in order to assure it is used safely and correctly. Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Did you inform your patient:	
• Of the expected teratogenic risk to the unborn child?	
• Of the hazards and necessary precautions associated with use of lenalidomide?	
• Not to share medication?	
• To return unused capsules to pharmacist?	
• Not to donate blood whilst taking lenalidomide, during treatment interruptions and for at least 7 days following discontinuation?	

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 prescribing physician of lenalidomide.

Prescriber First Name	
Prescriber Last Name	
Prescriber Signature	
Date	

Patient: please read thoroughly. If you agree, mark an X by 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 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 health problems (side effects) from lenalidomide.	
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	
I understand that I must return any unused lenalidomide to my pharmacy at the end of my treatment.	

Patient Confirmation

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

Patient Signature	
Date	

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported at –

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta

Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

AND

AM Mangion Ltd
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