Revlimid® Pregnancy Prevention Programme

Male Patients

Treatment Initiation Form

Introduction

This Treatment Initiation Form must be completed for each male patient 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 teroatogenic effect of 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 can cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name	
Patient Last Name	
Date of Birth	
Counselling Date	

Checklist for Counselling

This checklist is to assist you with counselling a male patient before they commence lenalidomide treatment in order to assure it is used safely and correctly.

Did you inform your patient:	
Of the expected teratogenic risk to the unborn child?	
Which are the effective contraceptive methods that she or the female partner of a male patient can use?	
Of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a risk of pregnancy?	
That he should inform his treating doctor immediately if his partner becomes pregnant whilst he is taking lenalidomide or shortly after he has stopped taking lenalidomide?	
Of the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain lenalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if partner is pregnant or of childbearing potential not using effective contraception?	
Of the need not to donate semen or sperm during treatment, during dose interruptions, and for at least 7 days following discontinuation?	
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?	
Can you confirm that your patient:	
Is capable of complying with contraceptive measures?	

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 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 the duration of my treatment, during dose interruptions and for at least 7 days after I stop lenalidomide even if I have had a vasectomy.	
I understand that if my partner does become pregnant whilst I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide I should inform my prescriber immediately and my partner should also consult her doctor immediately.	
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 or for at least 7 days after discontinuation of lenalidomide treatment.	
I know that I cannot donate semen or sperm while taking lenalidomide, during 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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New Street off Valletta Road
Luqa LQA6000, Malta
Email: pv@ammangion.com
Tel – 00 356 23976333

Marketing Authorisation Holder
Bristol-Myers Squibb Pharma EEIG