Revlimid® (lenalidomide) Pregnancy Prevention Programme

Woman of Childbearing Potential

Treatment Initiation Form

Introduction

This Treatment Initiation Form must be completed for each woman 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 need for effective contraception** for at least 4 weeks before starting treatment, throughout the entire duration of treatment, including during treatment interruptions, and for at least 4 weeks after the end of treatment, **or** absolute and continued abstinence?	
• That she must comply with advice on contraception even if she has amenorrhoea?	
• 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 consult rapidly if there is a risk of pregnancy?	
• The need to stop treatment immediately if female patient is suspected to be pregnant?	
• 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:	
• Was referred to a contraceptive consultant, if required?	
• Is capable of complying with contraceptive measures?	
• Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	
• Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	

* Refer to Healthcare Professional Brochure for criteria to determine if patient is a woman of non-childbearing potential.

** Refer to Healthcare Professional Brochure for information on contraception.

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE!

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 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 contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in case of dose interruptions, and for at least 4 weeks after the end of treatment.	
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 • the physician prescribing my lenalidomide	
I understand that before starting lenalidomide treatment I must have a pregnancy test. I will then have a pregnancy test at least every 4 weeks during treatment, and a test at least 4 weeks after the end of treatment.	
I understand that I must immediately stop taking lenalidomide and inform my prescriber if I become pregnant while taking this drug; or if I miss my menstrual period or experience any 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 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
Mangion House
New Street off Valletta Road
Luqa LQA6000, Malta
Email: pv@ammangion.com
Tel – 00 356 23976333

Marketing Authorisation Holder

Bristol-Myers Squibb Pharma EEIG