IMNOVID® (POMALIDOMIDE)

PREGNANCY PREVENTION PROGRAMME

WOMAN OF CHILDBEARING POTENTIAL

PATIENT CONFIRMATION DOCUMENT/TREATMENT INITIATION FORM

Medicines Authority Approval Date: *18 October 2023*

Introduction

This *Treatment Initiation Form* must be completed for each woman of childbearing potential prior to the initiation of their Imnovid® (pomalidomide) 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 pomalidomide. 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: Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. 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 Imnovid® (pomalidomide) is taken during pregnancy it may cause severe birth defects or death to an unborn baby.

Patient Details

Patient First Name	
Patient Last Name	
Patient Signature	
Counselling Date	

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential. I will comply with all my obligations and responsibilities as the prescribing physician of pomalidomide.

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 pomalidomide. 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 pomalidomide.	
I understand that I must not take pomalidomide 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 pomalidomide	
I understand that before starting pomalidomide 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 pomalidomide 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 pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	
I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible health problems (side effects) from pomalidomide.	
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	
I understand that I must return any unused pomalidomide to my pharmacy at the end of my treatment.	

REPORTING OF ADVERSE REACTIONS

The safe use of pomalidomide is of paramount importance. As part of BMS's ongoing safety monitoring, the company wishes to learn of Adverse Reactions that have occurred during the use of pomalidomide. Please contact AM Mangion Ltd immediately on Tel No 00356 23976333 and email pv@ammangion.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt

Patient Confirmation

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

Patient Signature	
Date	

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