IMNOVID® (POMALIDOMIDE)

PREGNANCY PREVENTION PROGRAMME

RISK AWARENESS FORM

This tool (previously checklist for counselling) can be utilized depending on implementation as agreed on with the National Competent Authority.

This tool can also be combined with the Patient Confirmation Document depending on implementation as agreed on with the National Competent Authority

Medicines Authority Approval Date: *18 October 2023*

RISK AWARENESS FORM FOR THE PATIENT BEING FULLY INFORMED OF/ABOUT THE SAFE USE OF IMNOVID® (POMALIDOMIDE)

This Risk Awareness Form is to assist you with counselling a patient before they commence Imnovid® (pomalidomide) treatment in order to assure it is used safely and correctly.

The purpose of the Risk Awareness 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 reactions associated with the use of Imnovid® (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.

Patient Details

Please complete this form in BLOCK CAPITAL LETTERS.

Patient's First Name	
Patient's Last Name	
Patient Signature	
Counseling Date	

Prescriber details

Please complete this form in BLOCK CAPITAL LETTERS.

Prescriber's First Name	
Prescriber's Last Name	
Prescriber's Signature	
Date	

Please choose the applicable column for the risk category of the patient and refer to the counselling messages provided.

Did you inform your patient:	**Male Patients**	**Women of Non-childbearing Potential***	**Women of Childbearing Potential**
1) Of the need to avoid foetal exposure		N/A	
2) That if she is pregnant or plans to be, she must not take pomalidomide	N/A	N/A	
3) That she understands the need to avoid pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	N/A	N/A	
4) That if she needs to change or stop using her method of contraception she should inform: a) the physician prescribing her contraception that she is taking Imnovid® b) the physician prescribing Imnovid® that she has stopped or changed her method of contraception	N/A	N/A	
5) Of the need for pregnancy tests (ie, before treatment) at least every 4 weeks during treatment and after treatment	N/A	N/A	
6) Of the need to stop Imnovid® immediately upon suspicion of pregnancy	N/A	N/A	
7) Of the need to contact their doctor immediately upon suspicion of pregnancy	N/A	N/A	
8) To not share the medicinal product with any other person			
9) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®			
10) That they should return the unused capsules to the pharmacist at the end of treatment			
11) That pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a WCBP not on effective contraception (even if the man has had a vasectomy)		N/A	N/A
12) That if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom		N/A	N/A
13) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®		N/A	N/A

Can you confirm that your patient:	Male Patients	Women of Non-childbearing Potential*	Women Childbearing Potential
1) Was referred to a contraceptive consultant, if required?	N/A	N/A	
2) Is capable of complying with contraceptive measures?		N/A	
3) Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilization?	N/A	N/A	
4) Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	N/A	N/A	

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

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!

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

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