Imnovid®▼(pomalidomide) Pregnancy Prevention Programme

Woman of Childbearing Potential Risk Awareness Form

IRELAND

Version 5.0

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

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RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF POMALIDOMIDE

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female prior to the initiation of their pomalidomide treatment.

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 drug reactions associated with the use of pomalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide as it is contraindicated in women of childbearing potential unless all terms of counselling are met.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding 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 pomalidomide is taken during pregnancy it is expected to cause severe birth defects or death to an unborn baby.

Patient Details

Patient's First Name:																							
Patient's Last Name:																							

Date of Birth:	*DD*	*MM*	*YYYY*	Counselling Date:	*DD*	*MM*	*YYYY*

Did you inform your patient:	**Woman of Childbearing Potential**
1) Of the expected teratogenic risk to the unborn child and the need to avoid foetal exposure.	*Tick*
2) That if she is pregnant or plans to be, she must not take Imnovid®.	*Tick*
3) Of the effective contraception she can use.	*Tick*
4) Of the need to avoid Imnovid® 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.	*Tick*
5) That if she needs to change or stop using her method of contraception she should inform: a) the prescriber prescribing her contraception that she is taking Imnovid®. b) the prescriber prescribing Imnovid® that she has stopped or changed her method of contraception.	*Tick*
6) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment.	*Tick*
7) Of the need to stop Imnovid® immediately upon suspicion of pregnancy.	*Tick*
8) Of the need to contact their prescriber immediately upon suspicion of pregnancy.	*Tick*
9) To not share the medicinal product with any other person.	*Tick*
10) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®.	*Tick*
11) That even if patient has amenorrhoea they must comply with advice on contraception.	*Tick*
12) Of hazards and necessary precautions associated with use of Imnovid®.	*Tick*
13) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
14) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Imnovid®.	*Tick*

Can you confirm your patient:

1) Was referred to a contraceptive consultant, if required?	YES	NO
2) Is capable of complying with contraceptive measures?	YES	NO
3) Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	YES	NO
4) Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	YES	NO

Contraceptive Referral

Contraceptive referral made on	DD	MM	YYYY
Contraceptive consultation conducted on	DD	MM	YYYY

Pregnancy Prevention

The patient has been established on one of the following for at least 4 weeks	
Implant	Tick
Levonorgestrel-releasing intrauterine system (IUS)	Tick
Medroxyprogesterone acetate depot	Tick
Tubal sterilisation	Tick
Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	Tick
Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	Tick
Committed to complete and absolute abstinence	Tick

Pregnancy Test

Date of last negative pregnancy test, prior to treatment initiation	DD	MM	YYYY

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE 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 THE PREGNANCY TEST IS NEGATIVE.

Prescriber Confirmation

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

Prescriber's First Name :																					
Prescriber's Last Name:																					

Prescriber's Signature:		Date:	*DD*	*MM*	*YYYY*

Patient: please read thoroughly and initial the adjacent box if you agree with 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.	*Patient initials*
I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.	*Patient initials*
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, or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional.	*Patient initials*
I understand that if I need to change or stop my method of contraception I will discuss this first with the healthcare professional prescribing my contraception method and the prescriber prescribing my pomalidomide.	*Patient initials*
I understand that before starting pomalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, 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.	*Patient initials*
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.	*Patient initials*
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the Imnovid® Patient Guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	*Patient initials*
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	*Patient initials*
I understand that even if I have amenorrhoea I must comply with advice on contraception.	*Patient initials*
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	*Patient initials*
I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide prescription, and that I must provide this to my pharmacy.	*Patient initials*
I understand that the 'Prescription Authorisation Form' contains non identifiable information about me, which will ensure pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of pomalidomide.	*Patient initials*

Patient Confirmation

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

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorisation Form (PAF) or Order Form) will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder and the distributor of Imnovid® for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or BMS at eudpo@bms.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	*DD*	*MM*	*YYYY*

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

Interpreter Signature:		Date:	*DD*	*MM*	*YYYY*

Bristol Myers Squibb™

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