Imnovid®▼(pomalidomide) Pregnancy Prevention Programme

Male 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 male 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 male patients receive counselling and education to be made aware of the risks of pomalidomide.

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:	Male
1) Of the need to avoid foetal exposure.	*Tick*
2) To not share the medicinal product with any other person.	*Tick*
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®.	*Tick*
4) That they should return the unused capsules to the pharmacist at the end of treatment.	*Tick*
5) Of the effective contraceptive measures he or his female partner can use.	*Tick*
6) That Imnovid® is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	*Tick*
7) That if his partner becomes pregnant, he should inform his treating prescriber immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	*Tick*
8) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Imnovid®.	*Tick*
9) Of hazards and necessary precautions associated with use of Imnovid®.	*Tick*
10) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Imnovid®.	*Tick*

Can you confirm your patient:

Is capable of complying with contraceptive measures?	*YES*	*NO*

Pregnancy Prevention

The patient confirms that:	
They will use a condom during intercourse with a woman of childbearing potential.	Tick
Their female partner is using an effective method of contraception.	Tick
Their female partner is of non-childbearing potential.	Tick
They are committed to complete and absolute abstinence.	Tick

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 have been told by my prescriber that I must NEVER have unprotected sexual contact with women who are pregnant or may become pregnant, whilst I am taking pomalidomide and for at least 7 days after stopping treatment.	Patient initials
I understand that pomalidomide 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 pomalidomide even if I have had a vasectomy.	Patient initials
I understand that if my partner does become pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide I should inform my prescriber immediately and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	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 know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after discontinuation of pomalidomide.	Patient initials
I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.	Patient initials
I have been informed about which are effective contraceptive methods that my female partner can use.	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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