Imnovid® (pomalidomide) Pregnancy Prevention Programme

Male Patients

Treatment Initiation Form

▼ ***This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via www.medicinesauthority.gov.mt/adrportal***

Introduction

This *Treatment Initiation Form* must be completed for each male patient 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 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	
Date of Birth, *Age or Age Group*	
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 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.	
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 also consult her doctor immediately.	
I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	
I have read the pomalidomide patient booklet 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 or for at least 7 days after stopping treatment.	
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.	
I understand that I must return any unused pomalidomide to my pharmacy at the end of my treatment.	

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	