Introduction

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their **Imnovid®** treatment. Retain a copy of this form with their medical records, and provide a photocopy 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 Imnovid. It does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure. This Treatment Initiation Form must be completed for each male patient prior to the initiation of their Imnovid treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: **Severe life-threatening birth defects.** If Imnovid® is taken during pregnancy it can cause **severe birth defects** or death to an unborn baby.

Patient Details

Patient First Name:																						
Patient Last Name:																						

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

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 pregnancy prevention	*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 above the nature, purpose and risks of the treatment associated with **Imnovid®**, especially the risks to women of childbearing potential.
I will comply with all my obligations and responsibilities as the prescribing physician of Imnovid®

Prescriber First Name :				
Prescriber Last Name:				
Prescriber Signature:		Date:	DD MM YYYY	

Patient: please read thoroughly and initial the adjacent box if you agree with the statement

I understand that Imnovid is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore Imnovid is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects can occur with the use of Imnovid. I have been warned by my doctor 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 Imnovid.	Patient initials
I have been told by my doctor that I must NEVER have unprotected heterosexual contact with women who are pregnant, or may become pregnant, while I am taking Imnovid and for 7 days after stopping treatment (even if I have had a vasectomy), unless the woman is practicing effective contraception	Patient initials
I agree to use condoms during sexual activity throughout treatment duration, during dose interruption, and for 7 days after cessation of treatment if my partner is pregnant or a woman of childbearing potential not using effective contraception (even if I have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa)	Patient initials
I know that I must inform my doctor immediately if I think that my partner may be pregnant while I am taking Imnovid or 7 days after I have stopped taking Imnovid and my partner should referred to a physician specialized or experienced in teratology for evaluation and advice	Patient initials
I understand that Imnovid will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the Imnovid Patient Booklet and understand the contents, including the information about other possible important health problems related to Imnovid	Patient initials
I understand that I cannot donate blood, semen or sperm during treatment while taking Imnovid (including dose interruptions) or for 7 days after stopping treatment.	Patient initials
I understand that I must return any unused Imnovid capsules to my pharmacy at the end of my treatment.	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 doctor can initiate my treatment with Imnovid®.

Patient Signature:		Date:	DD MM YYYY	