Introduction

This Treatment Initiation Form must be completed for each female patient of childbearing potential 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.

It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of Imnovid. Imnovid is contradicted in women of childbearing potential unless all terms of counselling are met.

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.

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 Referral

Pregnancy prevention referral required		*YES*	*NO*
Pregnancy prevention referral made	*DD*	*MM*	*YYYY*
Pregnancy prevention 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 sterilization	*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	*DD*	*MM*	*YYYY*

Imnovid® treatment cannot start until the patient has been established on effective method of pregnancy prevention for 4 weeks, or commits to complete and continuous abstinence, and obtains a negative pregnancy test.

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 understand that I must not take Imnovid if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use 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 pregnancy prevention I will discuss this first with the physician prescribing my pregnancy prevention method and the physician prescribing my Imnovid	Patient initials
I understand that before starting Imnovid treatment I must have a medically supervised pregnancy test. I will then have a pregnancy test 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 Imnovid and inform my treating doctor immediately upon suspicion of pregnancy while taking this drug (including dose interruptions); 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 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 know that I cannot donate blood 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