Revlimid® Treatment Initiation Form

Women of Childbearing Potential

This Treatment Initiation Form must be completed for each female patient of childbearing potential prior to the initiation of their Revlimid 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 assist both prescribers and patients to ensure all necessary steps are taken to prevent foetal exposure to lenalidomide and to assist in ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse effects associated with the use of lenalidomide. 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.

TREATMENT CANNOT START UNTIL PATIENT IS ESTABLISHED ON EFFECTIVE METHOD OF CONTRACEPTION FOR 4 WEEKS OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND PREGNANCY TEST IS NEGATIVE

Patient Name **Date of Birth**

	Insert √ or N/A
Inform of expected teratogenic risk to the unborn child	
Inform of the need for effective contraception 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 4 weeks after the end of treatment or absolute and continued abstinence	
Inform that that even if she has amenorrhoea she must comply with advice on contraception	
Confirm patient is capable of complying with contraceptive measures	
Inform of the expected consequences of pregnancy and the need to stop treatment and consult rapidly if there is a risk of pregnancy	
Confirm patient agrees to undergo pregnancy testing at 4 weekly intervals unless confirmed tubal sterilisation	
Inform of hazards and necessary precautions associated with use of Revlimid	
Inform patient not to share medication	
Inform to return unused capsules to pharmacist	
Inform not to donate blood whilst taking Revlimid or for one week after stopping	
Inform about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Revlimid	

Contraceptive referral

Contraceptive referral required	
Contraceptive referral made	
Contraceptive consultation completed	

Contraception
Patient is currently established on one of the following for at least 4 weeks

Implant	
Levonorgestrel-releasing intrauterine system (IUS)	
Medroxyprogesterone acetate depot	
Tubal Sterilisation	
Sexual intercourse with a vasectomised male partner only: vasectomy must be confirmed by two negative semen analyses	
Ovulation inhibitory progesterone only pill (i.e. desogestrel)	

Abstinence

Patient commits to complete and absolute abstinence	

Pregnancy test

Negative pregnancy test before starting treatment	

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

Physician Name
Physician Signature **Date**

Patient Name **Date of Birth**

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

My doctor has explained to me and I have understood the possible risks and the possible benefits associated with Revlimid® (lenalidomide). I have had the opportunity to ask questions and I have understood the answers provided to those questions.	*Patient initials*
I have received, read and understood the Patient Information Brochure.	*Patient initials*
I understand that Revlimid® (lenalidomide) has been prescribed for me personally and that I should not share it with any other person even if they have the same condition as me. I should store Revlimid® (lenalidomide) out of the reach of children.	*Patient initials*
I will return any unused capsules for my pharmacist.	*Patient initials*
I will not donate blood during treatment or for one week after stopping treatment	*Patient initials*
I understand that Revlimid® (lenalidomide) is expected to be harmful to the unborn child	*Patient initials*
I understand that unless I abstain from heterosexual intercourse (confirmed on a monthly basis) I will use effective contraception 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 4 weeks after the end of treatment.	*Patient initials*
Even if I do not experience monthly periods during treatment, I will still comply with the above contraceptive requirements	*Patient initials*
I agree to undergo pregnancy testing at 4 weekly intervals unless it has been confirmed to my doctor that I have undergone a tubal sterilization.	*Patient initials*
I will make all attempts to take my prescription to the pharmacist for dispensing within one working day from when my doctor provides me with the prescription.	*Patient initials*
I understand that during my lenalidomide treatment my pregnancy test date and result will be shared with my pharmacist every month.	*Patient initials*
In the event that I do become pregnant during treatment (or in the 4 weeks after stopping treatment) I will stop treatment with Revlimid® (lenalidomide) and seek advice from my doctor immediately	*Patient initials*
In the event that I do become pregnant during treatment (or in the 4 weeks after stopping treatment) I will stop treatment with Revlimid® (lenalidomide) and seek advice from my doctor immediately	*Patient initials*

Patient Confirmation
I confirm that I understand and will comply with the requirements of the Revlimid Pregnancy Prevention Programme, and I agree that my doctor can initiate my treatment with Revlimid

Patient Signature **Date**

