Lenalidomide Pregnancy Prevention Programme (PPP)

Male Treatment Initiation Form

UK

Introduction

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 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.

This Treatment Initiation Form must be completed for each male patient prior to the initiation of their lenalidomide treatment. The form should be retained with their medical records, and a copy provided to the patient.

Warning: Lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic active substance that causes severe life-threatening birth defects. Lenalidomide induced in monkeys malformations similar to those described with thalidomide. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans is expected. 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 lenalidomide is taken during pregnancy it is expected to 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 lenalidomide, especially the risks to women of childbearing potential. I will comply with my obligations and responsibilities as the prescribing physician of lenalidomide.

I confirm I have informed the patient (data subject) that their personal data will be communicated to Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance) in line with article 13 of the General (EU) 2016/679 Data Protection Regulation.

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 severe birth defects can occur with the use of lenalidomide. 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 lenalidomide.	Patient initials
I understand that lenalidomide 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 lenalidomide even if I have had a vasectomy.	Patient initials
I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking lenalidomide or within 7 days after I have stopped taking lenalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	Patient initials
I understand that lenalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the lenalidomide Patient Booklet and understand the contents, including the information about other possible health problems (side effects) associated with the use of lenalidomide.	Patient initials
I understand that I cannot donate blood while taking lenalidomide (including dose interruptions) or for at least 7 days after stopping treatment.	Patient initials
I know that I cannot donate semen or sperm while taking lenalidomide, during dose interruptions and for at least 7 days after discontinuation of lenalidomide treatment.	Patient initials
I understand that I must return any unused lenalidomide 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 lenalidomide.	Patient initials

Patient Confirmation

I confirm that I understand and will comply with the requirements of the lenalidomide Pregnancy Prevention Programme, and I agree that my prescriber can initiate my treatment with lenalidomide.

Patient Signature:		Date:	DD	MM	YYYY

The personal data provided by you will be processed by Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance). For further information on how to exercise your rights and how we process your data, visit out privacy policy available on our website www.accord-healthcare.com

Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent 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 lenalidomide.

Signed:		Name: (print)		Date:	DD	MM	YYYY

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