Lenalidomide
Pregnancy Prevention Programme (PPP)

Women of Childbearing Potential
Treatment Initiation Form

UK

Introduction

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

It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of lenalidomide. Lenalidomide is contraindicated 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 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.

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*

Contraceptive Referral

Contraceptive referral required		*YES*	*NO*
Contraceptive referral made	*DD*	*MM*	*YYYY*
Contraceptive 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 sterilisation	*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*

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

Woman of Childbearing Potential Treatment Initiation Form

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 prescriber 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 are expected to 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 I must not take lenalidomide if I am pregnant or plan to become pregnant.	Patient initials
I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment and even in the 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 contraception I will discuss this first with the physician prescribing my contraception and the physician prescribing my lenalidomide.	Patient initials
I understand that before starting the lenalidomide treatment I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilisation, I will then have a pregnancy test at least 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 lenalidomide and inform my prescriber if I become pregnant while taking this drug; 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 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 important health problems (side effects) associated with the use of lenalidomide.	Patient initials
I know that I cannot donate blood while taking lenalidomide (including dose interruptions) and for at least 7 days after stopping 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 understand that even if I have amenorrhoea I must comply with advise on contraception.	Patient initials
I have been information 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 our 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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