REVLIMID® ▼
(lenalidomide)

Pregnancy Prevention Programme (PPP)

Woman of Childbearing Potential Treatment Initiation Form

UK
Version 10

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Bristol-Myers Squibb (BMS) Medical Information on 0800 731 1736 or medical.information@bms.com.

Introduction

This Treatment Initiation Form must be completed for each woman 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.

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

Revlimid treatment cannot start until the patient has been established on at least one effective method of contraception 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 Revlimid, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescriber of Revlimid.

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

Statement	
I understand that severe birth defects are expected to occur with the use of Revlimid. 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 Revlimid.	*Patient initials*
I understand that I must not take Revlimid 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 Revlimid.	*Patient initials*
I understand that before starting the Revlimid 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 Revlimid 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 Revlimid will be prescribed ONLY for me. I must not share it with ANYONE.	*Patient initials*
I have read the Revlimid Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of Revlimid.	*Patient initials*
I know that I cannot donate blood while taking Revlimid (including dose interruptions) and for at least 7 days after stopping treatment.	*Patient initials*
I understand that I must return any unused Revlimid capsules to my pharmacy at the end of my treatment.	*Patient initials*
I understand that even if I have amenorrhoea I must comply with advice on contraception.	*Patient initials*
I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Revlimid.	*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 prescriber can initiate my treatment with Revlimid.

This form will be kept by your doctor. Your personal data (collected on the prescription authorisation form or "PAF") will be processed by Bristol-Myers Squibb Pharma EEIG ("BMS"), as the marketing authorisation holder of Revlimid for the purpose(s) of managing the Pregnancy Prevention Programme.

Your data will be kept for as long as necessary, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data please contact your doctor or BMS at: eudpo@bms.com. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

Patient Signature:		Date:	DD	MM	YYYY

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 Revlimid.

Interpreter Signature:		Name: (print)		Date:	DD	MM	YYYY

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