Pomalidomide
Pregnancy Prevention Programme (PPP)

Women of Childbearing Potential
Risk Awareness Form

UK
Version 1

Healthcare professionals are asked to report any suspected adverse reactions using the Yellow Card Scheme
via https://yellowcard.mhra.gov.uk/ or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse reactions should also be reported to Accord Medical Information on 01271 385257 or medinfo@accord-healthcare.com

Risk Awareness Form for counselling the patient to ensure the patient is fully informed about the safe use of pomalidomide

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female patient of childbearing potential prior to the initiation of their pomalidomide treatment. This form must be completed by a physician with expertise in managing immunomodulatory drugs.

The purpose of the Risk Awareness 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 pomalidomide. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide. Pomalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

This form should be retained with their medical records, and a copy provided to the patient.

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: Pomalidomide must not be taken during pregnancy since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. 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 pomalidomide 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

Did you inform your patient	WCBP
1 Of the need to avoid foetal exposure	
2 That if she is pregnant or plans to be, she must not take pomalidomide	
3 That she understands the need to avoid pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment	
4 That if she needs to change or stop using her method of contraception she should inform (a) the physician prescribing her contraception that she is taking pomalidomide (b) the physician prescribing pomalidomide that she has stopped or changed her method of contraception	
5 Of the need for pregnancy tests (i.e. before treatment) at least every 4 weeks during treatment and after treatment	
6 Of the need to stop pomalidomide immediately upon suspicion of pregnancy	
7 Of the need to contact their doctor immediately on suspicion of pregnancy	
8 To not share the medicinal product with any other person	
9 That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide	
10 That they should return the unused capsules to the pharmacist at the end of treatment	

Can you confirm your patient

1	Was referred to a contraceptive consultant, if required?	Y/N
2	Is capable of complying with contraceptive measures?	Y/N
3	Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	Y/N
4	Has a negative pregnancy test before staring treatment even if absolute and continued abstinence?	Y/N

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
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 pills (i.e. desogestrel)
Committed to complete and absolute abstinence

Pregnancy Test

Date of last negative pregnancy test	DD	MM	YYYY

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUOUS ABSTINENCE, AND PREGNANCY TEST IS NEGATIVE.

Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose and risks of the treatment associated with pomalidomide, especially the risks to women of childbearing potential.

I will comply with my obligations and responsibilities as the prescriber of pomalidomide.
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 pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child.	Patient initials
I understand that severe birth defects are expected to occur with the use of pomalidomide. 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 pomalidomide.	Patient initials
I understand that I must not take pomalidomide 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 pomalidomide.	Patient initials
I understand that before starting the pomalidomide 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 pomalidomide 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 pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	Patient initials
I have read the pomalidomide Patient Booklet and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide.	Patient initials
I know that I cannot donate blood while taking pomalidomide (including dose interruptions) and for at least 7 days after stopping treatment.	Patient initials
I understand that I must return any unused pomalidomide 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 informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	Patient initials

Patient Confirmation

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

This form will be kept by your doctor. Your personal data collected on the Prescription Authorisation Form (PAF) will be processed by Accord-UK Ltd, as the marketing authorisation holder of pomalidomide for the purpose 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 visit our privacy policy available on our website www.accord-healthcare.com

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 pomalidomide.

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

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