Pomalidomide Risk Awareness Form

For All Patients
(Women of childbearing potential, Women of non-childbearing potential and Male)

IRELAND
Version 1.0

This Risk Awareness Form must be completed for each patient prior to the initiation of their pomalidomide treatment.

It is mandatory that all patients receive counselling and education to be made aware of the risks of pomalidomide. In particular, pomalidomide is contraindicated in women of childbearing potential unless all terms of counselling are met.

The aim 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 drug reactions associated with the use of pomalidomide. 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.

Patients:
Women of childbearing potential: Complete Part A and Part B ***Men: Complete Part A and Part C***

Woman of non-childbearing potential: Complete Part A

Prescribers:
For Women of childbearing potential complete Part D ***For male patients complete Part E***

The form should be retained with the patient's medical records, and a copy provided to the patient.

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 and Last Name	
Date of Birth	DD MM YYYY

Prescriber details

Prescriber First and Last Name	
Counselling Date	DD MM YYYY

PATIENT: PLEASE READ THOROUGHLY AND TICK THE ADJACENT BOX IF YOU AGREE WITH THE STATEMENT

PART A (all Patients-Women of childbearing potential, Women of non-childbearing potential and Male)	
• I understand that pomalidomide is expected to be harmful to an unborn baby and that severe birth defects may 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.	TICK
• I have read the pomalidomide patient guide and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.	TICK
• I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.	TICK
• I understand that I must return any unused capsules to my pharmacy at the end of my treatment.	TICK
• I understand that I cannot donate blood during treatment with pomalidomide, including dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.	TICK
• I understand that my prescriber will provide me with a completed 'Prescription Authorisation Form' with each pomalidomide prescription, and that I must provide this to my pharmacy.	TICK
• I understand that the 'Prescription Authorisation Form' contains non-identifiable information about me, which will ensure pomalidomide is dispensed safely. The information may also be used by the Marketing Authorisation Holder and the distributor for the product I receive and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of Pomalidomide*.	TICK

PART B (only for Women of Childbearing Potential)	
• I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.	TICK
• 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 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.	TICK
• I understand that if I need to change or stop my method of contraception, I will discuss this first with the presciber prescribing my contraception and the presciber prescribing my pomalidomide.	TICK
• I understand that that even if I have amenorrhoea I must comply with advice on contraception.	TICK
• I understand that before starting 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.	TICK
• I understand that I must immediately stop taking pomalidomide and inform my prescriber if I become pregnant or suspect I am pregnant while taking this drug or within 4 weeks of treatment end, if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	TICK

PART C (only for Male Patients)	
• I have been told by my prescriber that I must NEVER have unprotected sexual contact with women who are pregnant or may become pregnant, whilst I am taking pomalidomide and for at least 7 days after stopping treatment.	TICK
• I understand that pomalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she does not 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 pomalidomide even if I have had a vasectomy.	TICK
• I understand that if my partner does become pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide I should inform my prescriber immediately and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	TICK
• I understand that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after stopping treatment.	TICK
• I have been informed about effective contraceptive methods that my female partner can use.	TICK

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.

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.

Interpreter name and signature:	**Date:** DD MM YYYY

*****Your personal data is used solely for the purpose of entering you into the Pomalidomide Pregnancy Prevention Programme and is processed by the Marketing Authorisation Holder (MAH) of the pomalidomide product you receive, its third-party service providers and any worldwide Affiliates the MAH may have, for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes. Third party service providers include, for example, the distributor of the pomalidomide product you receive.
Your pharmacist can confirm the details of the MAH for the pomalidomide product you are given and this will also be mentioned on the packaging and package leaflet. Queries on how your personal data will be processed can be directed to the MAH in question, by consulting their publicly available information (e.g., on their website) which details how they process your personal data and provides a contact point for any queries in relation to their use of your personal data.

PRESCRIBER: FOR FEMALE PATIENTS OF CHILDBEARING POTENTIAL (PART D) AND MALES (PART E)

PART D (For Women of Childbearing Potential)	
Did you inform your patient:	
1) Of the expected teratogenic risk to the unborn child and the need to avoid foetal exposure.	TICK
2) That if she is pregnant or plans to be, she must not take Pomalidomide.	TICK
3) Of the effective contraception she can use.	TICK
4) Of 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.	TICK
5) That if she needs to change or stop using her method of contraception she should inform: a. the prescriber prescribing her contraception that she is taking Pomalidomide. b. the prescriber prescribing Pomalidomide that she has stopped or changed her method of contraception.	TICK
6) Of the need for pregnancy tests (i.e., before treatment) at least every 4 weeks during treatment and after treatment.	TICK
7) Of the need to stop Pomalidomide immediately upon suspicion of pregnancy.	TICK
8) Of the need to contact their prescriber immediately upon suspicion of pregnancy.	TICK
9) To not share the medicinal product with any other person.	TICK
10) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
11) That even if patient has amenorrhoea they must comply with advice on contraception.	TICK
12) Of hazards and necessary precautions associated with use of Pomalidomide.	TICK
13) That they should return the unused capsules to the pharmacist at the end of treatment.	TICK
14) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Pomalidomide.	TICK

Can you confirm your patient:		
Was referred to a contraceptive consultant, if required?	YES	NO
Is capable of complying with contraceptive measures?	YES	NO
Agreed to undergo pregnancy testing at least in 4 weekly intervals unless confirmed tubal sterilisation?	YES	NO
Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	YES	NO
Contraceptive referral for Women of Childbearing Potential		
• Contraceptive referral required	YES	NO
• Date Contraceptive referral made	DD MM YYYY	
• Date Contraceptive consultation conducted on	DD MM YYYY	
Pregnancy Prevention for Women of Childbearing Potential		
The patient has been established on one of the following for at least 4 weeks		
• Implant	TICK	
• Levonorgesterel-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 (e.g., desogestrel)	TICK	
• Committed to complete and absolute abstinence	TICK	
Pregnancy Test		
Date of last negative pregnancy test	DD MM YYYY	
POMALIDOMIDE TREATMENT CANNOT START UNTIL THE PATIENT HAS BEEN ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR ATLEAST 4 WEEKS, OR COMMITS TO COMPLETE AND CONTINUOUS ABSTINENCE, AND OBTAINS A NEGATIVE PREGNANCY TEST.		

PART E for Male Patients	
Did you inform your patient:	
1) Of the need to avoid foetal exposure.	TICK
2) To not share the medicinal product with any other person.	TICK
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
4) That they should return the unused capsules to the pharmacist at the end of treatment.	TICK
5) Of the effective contraceptive measures he or his female partner can use.	TICK
6) That Pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not on effective contraception (even if the man has had a vasectomy) throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment.	TICK
7) That if his partner becomes pregnant, he should inform his treating prescriber immediately, his partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.	TICK
8) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	TICK
9) Of hazards and necessary precautions associated with use of Pomalidomide.	TICK
10) Of the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with Pomalidomide.	TICK

Can you confirm your patient:		
Is capable of complying with contraceptive measures?	YES	NO
Pregnancy Prevention for Male Patients		
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 contraceptive method	TICK	
• Their female partner is of non-childbearing potential	TICK	
• They are committed to complete and absolute abstinence	TICK	

Prescribers Confirmation

I confirm that:

- 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 have fully explained to the patient named above the importance of compliance with the requirements of the pomalidomide Pregnancy Prevention Programme.
- I will comply with all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber signature:	**Date:** DD MM YYYY