

# Pomalidomide Pregnancy Prevention Programme

## Male Risk Awareness Form

**IRELAND**

**Version 6.0**



## 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 contraception.	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 overleaf the nature, purpose and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.

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

Prescriber's First Name :																				
Prescriber's Last Name:																				
Prescriber's 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 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.	Patient initials
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.	Patient initials
I understand that pomalidomide 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 pomalidomide even if I have had a vasectomy.	Patient initials
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.	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 Guide and understand the contents, including the information about other possible 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 know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions and for at least 7 days after discontinuation of pomalidomide.	Patient initials
I understand that I must return any unused pomalidomide 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 pomalidomide.	Patient initials
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.	Patient initials
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, the distributor of the product and the Health Products Regulatory Authority (HPRA) to evaluate the safe use of 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.

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 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.

Patient Signature:		Date:	DD	MM	YYYY
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### Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent/carer 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 Signature:		Date:	DD	MM	YYYY
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