

Pomalidomide ▼ **Pregnancy Prevention Programme**

Male Risk Awareness Form

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

Approved by the Malta Medicines Authority on the 2nd of April 2026.

Reporting of Adverse Reactions

Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

or

Adalvo Limited
Malta Life Sciences Park,
Sir Temi Zammit,
Building 1, Level 4,
San Gwann Industrial Estate,
San Gwann, SGN 3000,
Malta
Email: pharmacovigilance@adalvo.com
Tel: +0040 727251514

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 male prior to the initiation of their pomalidomide treatment. This form must be completed by a physician experienced 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 drug reactions associated with the use of pomalidomide. It is mandatory that male patients receive counselling and education to be made aware of the risks of Pomalidomide.

The form should be retained with their medical records, and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding 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's First Name:

Patient's Last Name:

Date of Birth:

DD MM YYYY

Counselling Date:

DD MM YYYY

1) Of the need to avoid foetal exposure.	<i>Tick</i>
2) To not share the medicinal product with any other person.	<i>Tick</i>
3) That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	<i>Tick</i>
4) That they should return the unused capsules to the pharmacist at the end of treatment.	<i>Tick</i>
5) That pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a WCBP not on effective contraception (even if the man has had a vasectomy).	<i>Tick</i>
6) That if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom.	<i>Tick</i>
7) That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of Pomalidomide.	<i>Tick</i>

Pregnancy Prevention

The patient confirms that:	<i>Tick</i>
They will use a condom during intercourse with a woman of childbearing potential.	<i>Tick</i>
Their female partner is using an effective method of contraception.	<i>Tick</i>
Their female partner is of non-childbearing potential.	<i>Tick</i>
They are committed to complete and absolute abstinence.	<i>Tick</i>

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 all my obligations and responsibilities as the prescriber of pomalidomide.

Prescriber's First Name:

Prescriber's 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.

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.

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.

I know that I must inform my prescriber immediately if I think that my partner may be pregnant whilst I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide and my partner should be referred to a physician specialised or experienced in teratology for evaluation and advice.

I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.

I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide.

I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.

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.

I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.

I have been informed about which are effective contraceptive methods that my female partner can use.

I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.

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 will be processed by Adalvo Ltd, as the marketing authorisation holder of Pomalidomide 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 Adalvo Ltd at Email: pharmacovigilance@adalvo.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 pomalidomide

Interpreter Signature:

Date:

DD MM YYYY