

Pomalidomide Rowex Pregnancy Prevention Programme Risk Awareness From- Women with Childbearing Potential

Pomalidomide

Approved by the Malta Medicines Authority on the 13th January 2026.

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with pomalidomide. Please send them immediately. Contact details are given below.

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

Marketing Authorisation Holder:
Rowex Limited
Tel: 0877941968
Email: adverse.event.ireland@sandoz.net

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:

1. Was referred to a contraceptive consultant, if required?	YES	NO
2. Is capable of complying with contraceptive measures?	YES	NO
3. Agreed to undergo pregnancy testing at least in 4-weekly intervals unless confirmed tubal sterilisation?	YES	NO
4. Had a negative pregnancy test before starting treatment even if absolute and continued abstinence?	YES	NO

Contraceptive Referral

Contraceptive referral made on	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 vasectomized 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

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 send or may provide me with a completed 'Prescription Authorisation Form' with each pomalidomide prescription for the pharmacy	Patient Initials
I understand that the 'Prescription Authorisation Form' contains non-identifiable information about me, which will ensure pomalidomide is dispensed safely. This information may be used by the Marketing Authorisation Holder and the distributor for the product I receive, and the Malta Medicines Authority (MMA) 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 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.

Patients 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.

Signed:		Name: (Print)		Date	DD	MM	YYYY
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Important Safety Information:

This risk minimisation material is provided by Rowex Ltd. For further information, please refer to the Summary of Product Characteristics (SmPC) for the respective medicinal product from the relevant Marketing Authorisation Holder.