

Pomalidomide Rowex Pregnancy Prevention Programme Patient Pocket Information Guide

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

**Patient Pocket Information Guide
Pomalidomide**

Information for Patients and Healthcare Professionals:

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

Pomalidomide is structurally related to thalidomide and is expected to cause severe birth defects or death to an unborn baby therefore:

- Women of childbearing potential must always use effective contraception
- Women of childbearing potential must have pregnancy tests prior to starting treatment and every 4 weeks, prior to each prescription, to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation
- Male patients with pregnant partners or partners of childbearing potential not using effective contraception must always use condoms (even if man has had a vasectomy)
- If a female patient or female partner of a male patient suspects they are pregnant, they must contact their prescriber immediately
- You **MUST** tell your prescriber immediately if you experience any symptom that causes concern

For complete information on the side effects of pomalidomide, patients should read the Package Leaflet and HCPs should read the Summary of Product Characteristics.

Information for Healthcare Professionals:

Prescription Details

Has the patient received counselling?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Childbearing potential assessment	<input type="checkbox"/> WCBP* <input type="checkbox"/> WNCBP** <input type="checkbox"/> Male
If the patient is a WCBP is she using effective contraception?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If the patient is male, is he using condoms, if required?	<input type="checkbox"/> Yes <input type="checkbox"/> No

* *Women of Childbearing Potential*

** *Women of Non-childbearing Potential*

A completed Prescription Authorisation Form must accompany each prescription to confirm that the patient continues to use effective contraception (if required) and, in the case of a WCBP, is having a pregnancy test every 4 weeks before each prescription to ensure they are not pregnant.

Information for Healthcare Professionals:

Prescription Details

This patient is receiving pomalidomide for treatment of:

Emergency Contact Information:

Emergency Prescriber Contact:

Telephone number during office hours:

Telephone number after office hours:

Further information is available in the patient guide.