

Pomalidomide Rowex Patient Card

Approved by the Malta Medicines Authority on the 23rd September 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

Marketing Authorisation Holder:

Rowex Limited

Tel: 0877941968

Email: adverse.event.ireland@sandoz.net

Sandoz Patient Safety

Pomalidomide

1 mg, 2 mg, 3 mg, and 4 mg hard gelatin capsules

Active substance(s) (INN or common name): Pomalidomide

Product(s) concerned (brand name(s)): Pomalidomide Rowex 1 mg, 2 mg, 3 mg, and 4 mg hard gelatin capsules

Document status: Draft

Applicable RMP version number: 1.3

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Confidential

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without the consent of Sandoz

Prescription Details:				[Nationally completed name] (Pomalidomide)																																														
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 5px;">Prescription Date</td> <td style="width: 10%; padding: 5px; text-align: center;"><i>DD</i></td> <td style="width: 10%; padding: 5px; text-align: center;"><i>MM</i></td> <td style="width: 45%; padding: 5px; text-align: center;"><i>YYYY</i></td> </tr> </table>				Prescription Date	<i>DD</i>	<i>MM</i>	<i>YYYY</i>	This patient is on pomalidomide.																																										
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 35%; padding: 5px;">Has the patient received counseling?</td> <td style="width: 65%; padding: 5px; text-align: center;">Yes/No</td> </tr> </table>				Has the patient received counseling?	Yes/No	Information for Patients: - You MUST tell your prescriber immediately if you experience any symptom that causes concern. - You MUST inform your prescriber immediately if you suspect that you or your female partner may be pregnant.																																												
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This patient is receiving pomalidomide for treatment of: ☐ Multiple myeloma (MM) OR ☐ Relapsed/refractory MM																																																		
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%; padding: 5px;">Pregnancy Test Date (DD/MM/YYYY)</th> <th style="width: 20%; padding: 5px;">Pregnancy Test Result (+/-)</th> <th style="width: 50%; padding: 5px;">Is the patient using effective contraception? (Y/N)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>				Pregnancy Test Date (DD/MM/YYYY)	Pregnancy Test Result (+/-)	Is the patient using effective contraception? (Y/N)																																											Information for Patients and Healthcare Professionals: Pomalidomide is an immunomodulator and an expected human teratogen. Therefore: - women of childbearing potential must use at least one effective method of contraception, and male patients with pregnant partners or partners of childbearing potential not using effective contraception must use condoms (even if the man has had a vasectomy) - women of childbearing potential must have regular pregnancy tests to ensure that they are not pregnant, except in the case of confirmed tubal sterilisation - if a female patient or female partner of a male patient suspects they are pregnant, they must contact their doctor immediately. For complete information on the side effects of pomalidomide, patients should read the Package Leaflet and Patient Brochure. Healthcare professionals should read the Summary of Product Characteristics. Of note, pomalidomide may cause bleeding or bruising without a cause, including bleeding within the skull, nosebleeds and bleeding from the bowels or stomach. As such, there is a need for regular blood tests.	
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P: woman of childbearing potential; **WNCBP:** woman of non-childbearing potential.