

Pomalidomide Rowex Pregnancy Prevention Programme Pregnancy Reporting From Pomalidomide

Pomalidomide

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, mi.ireland@sandoz.net

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

- **NOTE:** Please use the first three letters of the month (e.g.: JAN)

Background Information on Reason for Pregnancy

Was patient erroneously considered not to be of childbearing potential? Yes No

If yes, state reason for considering not to be of childbearing potential

- | | | |
|---|---------------------------|--------------------------|
| <input type="radio"/> Age \geq 50 years and naturally amenorrhoeic* for \geq 1 year | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Premature ovarian failure confirmed by a specialist gynecologist | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Previous bilateral salpingo-oophorectomy, or hysterectomy | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> XY genotype, Turner syndrome, uterine agenesis. | <input type="radio"/> Yes | <input type="radio"/> No |

Indicate from the list below what contraception was used

- | | | |
|--|---------------------------|--------------------------|
| <input type="radio"/> Implant | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Levonorgestrel-releasing intrauterine system | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Medroxyprogesterone acetate depot | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Tubal sterilization (specify below) | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Tubal ligation | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Tubal diathermy | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Tubal chips | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Ovulation inhibitory progesterone-only pills (i.e. desogestrel) | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Other progesterone-only pills | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Combined oral contraceptive pill | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Other intra-uterine devices | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Condoms | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Cervical cap | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Sponge | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Withdrawal | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Other | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> None | <input type="radio"/> Yes | <input type="radio"/> No |

Indicate from the list below the reason for contraceptive failure

- | | | |
|---|---------------------------|--------------------------|
| <input type="radio"/> Missed oral contraception | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Other medication or intercurrent illness interacting with oral contraception | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Identified mishap with barrier method | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Unknown | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Had the patient committed to complete and continuous abstinence | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Was the drug started despite patient already being pregnant | <input type="radio"/> Yes | <input type="radio"/> No |
| <input type="radio"/> Did patient receive educational materials on the potential risk of teratogenicity | <input type="radio"/> Yes | <input type="radio"/> No |

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Maternal Past Medical History

Condition	Dates	Treatment	Outcome																		
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Maternal Current Medical Conditions

Condition	From	Treatment												
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Maternal Social History

Alcohol Yes No Tobacco Yes No IV or recreational drug use Yes No

If yes, amount/units per day: If yes, amount per day: If yes, provide details:

