

Sandoz Patient Safety**Isotretinoin****Approved by the Malta Medicines Authority on the 2nd of October 2026****Content Pharmacist Checklist****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

Pharmacist Checklist - Guidance for dispensing Isotretinoin

Isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to Isotretinoin, even for short periods of time, presents a high risk of very severe and serious congenital malformations and an increased risk of spontaneous abortion.

Isotretinoin is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions of the Isotretinoin Pregnancy Prevention Programme (PPP) are fulfilled.

If you are aware that a pregnancy has occurred in a woman treated with Isotretinoin, treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within one month of stopping Isotretinoin she should be referred to her prescribing doctor.

Patient Reminder Card

Counsel all patients (male and female) on the patient reminder card which is included in the product packaging. In the event that broken bulk dispensing cannot be avoided, the patient should be provided with a copy of the package leaflet and the patient reminder card.

As pharmacist, you should only dispense Isotretinoin after checking the following information:

This material is provided by Rowex Ltd as a licence requirement for this medicine and forms part of the Isotretinoin Risk Management Plan.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. HCPs are asked to report any suspected adverse reactions. See box below for details on how to report.

For women of child-bearing potential:	
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for Isotretinoin should ideally be limited to a 30-day supply.	☐
Ideally, a negative pregnancy test, issuing a prescription and dispensing of Isotretinoin should occur on the same day.	☐
All patients should be instructed:	
Never to give the Isotretinoin to another person.	☐
To return any unused capsules to their pharmacist at the end of treatment.	☐
Not to donate blood during Isotretinoin therapy and for one month after discontinuation due to the potential risk to the fetus of a pregnant transfusion recipient	☐

Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. HCPs are asked to report any suspected adverse events or

reactions. In the event of a suspected adverse event, please report it to:

Rowex Limited

Tel: 0877941968

Email: adverse.event.ireland@sandoz.net

Alternatively, suspected adverse reactions should be reported 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

Further Information

For additional electronic copies of this risk minimization material, refer to:

www.medicinesauthority.gov.mt and download the required material. Alternatively, if you would like hard copies, please contact Rowex Limited, Tel: 0877941968, Email:

adverse.event.ireland@sandoz.net. For further information about Isotretinoin, please contact

Medical Information at Rowex Ltd by telephone Tel: 0877941968 or Email:

adverse.event.ireland@sandoz.net