

Sandoz Patient Safety

Isotretinoin

Content Physician Checklist

Approved by the Malta Medicines Authority on the 2nd of October 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

Physician Checklist /Acknowledgement Form for Prescribing Isotretinoin to Female Patients

The potential for pregnancy must be assessed for all girls and women of childbearing potential treated with Isotretinoin

Is the patient a girl or woman of childbearing potential?	Yes ☐	No ☐
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A woman or a girl of childbearing potential who could become pregnant is defined as follows:

A sexually developed women who:

- 1) has not undergone a hysterectomy or bilateral oophorectomy
- 2) has had one or more menstrual periods in the past 24 consecutive months

This form is to be completed by the Physician and patient at initial and follow-up visits for all female patients prescribed Isotretinoin. The signed document should be kept with patient notes to document compliance with the Isotretinoin Pregnancy Prevention Programme. After completion, a copy of this document should be given to the patient.

Isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to Isotretinoin, even for short periods, presents a great risk of very severe and serious congenital malformations. Isotretinoin is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions of the Isotretinoin Pregnancy Prevention Programme are fulfilled.

As the prescribing doctor, you must ensure that the teratogenic risk and necessary precautions are fully understood and acknowledged by all female patients before treating them with Isotretinoin.

Please refer to the patient reminder card in the pack to support your discussion with the patient.

Review the below statements, explain them with your patient and ensure that she understands and acknowledges the risks and necessary precautions related to the use of Isotretinoin. If the answer to any of these questions is **NO**, Isotretinoin must not be prescribed.

To be completed by the physician and patient		
<i>Review the statements given below, explain them to the patient and record the confirmation given by both the doctor and the patient. If the answer to any of the questions is NO, isotretinoin must not be prescribed.</i>	<i>THE DOCTOR CONFIRMS that the patient has been informed</i>	<i>THE PATIENT CONFIRMS that she has understood</i>
I confirm that the patient is prescribed Isotretinoin because she is suffering from a severe form of acne (such as nodular or conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy.	Yes ☐ No ☐	Yes ☐ No ☐

I confirm that I have discussed the following information with my patient:		
Teratogenicity		
Isotretinoin belongs to a class of drugs (retinoids) known to cause severe birth defects and serious fetal malformations, including central nervous system abnormalities, facial dysmorphism, cleft palate, external ear abnormalities, eye abnormalities, cardiovascular abnormalities, thymus gland abnormality and parathyroid gland abnormalities.	Yes ☐ No ☐	Yes ☐ No ☐
Isotretinoin increases the risk of spontaneous abortion when taken during pregnancy.	Yes ☐ No ☐	Yes ☐ No ☐
Isotretinoin must not be used in pregnancy, and the patient must not become pregnant whilst taking this medication, and for 1 month after stopping treatment.	Yes ☐ No ☐	Yes ☐ No ☐
Contraception		
The need for consistent and correct use, without interruption, of at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary user-dependent methods of contraception (e.g. oral contraceptive and barrier method) before and during treatment.	Yes ☐ No ☐	Yes ☐ No ☐
The need for contraception, as described above, for at least 1 month before treatment, throughout the entire duration of treatment and for at least 1 month after stopping treatment as the risk persists until the product is completely eliminated, which is within 1 month following the end of treatment.	Yes ☐ No ☐	Yes ☐ No ☐
I have provided advice on contraception which is appropriate for the patient or I have referred her for contraception services as appropriate and she has consented to use it throughout the risk period (1 month before treatment until 1 month following treatment).	Yes ☐ No ☐	Yes ☐ No ☐
The patient is aware of the risks when contraception fails.	Yes ☐ No ☐	Yes ☐ No ☐
Pregnancy Testing & Monthly Prescriptions		
The need for a medically supervised pregnancy test at least 1 month after the patient has started using contraception and shortly (preferably a few days) prior	Yes ☐ No ☐	Yes ☐ No ☐

to the first prescription for Isotretinoin to ensure that the patient is not pregnant when she starts treatment. The first prescription for isotretinoin can only be given after the patient has had at least one negative medically supervised pregnancy test (chorionic gonadotropin (hCG)).		
The need for prescription to ideally be limited to 30 days, in order to support regular follow up, including pregnancy testing and monitoring.	Yes ☐ No ☐	Yes ☐ No ☐
The need for pregnancy testing during (ideally monthly) and 1 month after stopping treatment, as the risk of severe and serious fetal malformations persists until the product is completely eliminated.	Yes ☐ No ☐	Yes ☐ No ☐
The need to contact her doctor immediately in case of unprotected sex, missed period, suspected or inadvertent pregnancy during treatment or within 1 month after stopping treatment.	Yes ☐ No ☐	Yes ☐ No ☐
The need to stop treatment immediately in case of suspected or inadvertent pregnancy and need for patient referral to an expert physician specialized or experienced in teratology for advice (in case of pregnancy).	Yes ☐ No ☐	Yes ☐ No ☐
I have referred the patient to the patient reminder card included in the pack.	Yes ☐ No ☐	Yes ☐ No ☐
The contraceptive methods and pregnancy test results are documented in the patient's medical record.	Yes ☐ No ☐	Yes ☐ No ☐
The patient has received a copy of the checklist and the patient alert card.	Yes ☐ No ☐	Yes ☐ No ☐
Other Precautions		
Isotretinoin must not be shared with others.	Yes ☐ No ☐	Yes ☐ No ☐
The patient must not donate blood during treatment with Isotretinoin and for 1 month after discontinuation due to the potential risk to the fetus of a pregnant transfusion recipient.	Yes ☐ No ☐	Yes ☐ No ☐
Doctor Name:	Signature	Date

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MAH, Rowex Limited, Tel: 0877941968, Email: adverse.event.ireland@sandoz.net who will follow up with you to record the pregnancy outcome.

Patient Name:	Patient Signature	Date:
Parent/Legal Guardian (if patient is under the age of 16):	Parent/Legal Guardian Signature:	Date:

Signature of parent or legal guardian is necessary if the patient is under the age of 16.

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: www.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 www.medicinesauthority.gov.mt.