

Sandoz Patient Safety**Isotretinoin****Patient Card****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

Isotretinoin Contraception and Pregnancy Prevention

Patient Reminder Card

Doctor's name:

Telephone:

Notes:

Reporting of side effects

if you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the Isotretinoin Package leaflet. You can also report side effects directly (See details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Please report side effects to:

Rowex Limited

Tel: 0877941968

Email: adverse.event.ireland@sandoz.net

Or report to : www.medicinesauthority.gov.mt

Further Information

Please read the Isotretinoin package leaflet for further information on this medicine. If you have any questions about this medicine. please talk to your doctor or pharmacist.

<u>Reminder for all patients</u>
This medication has been prescribed to you only.
Do not give it to anybody else and return all unused capsules to the pharmacy.
You must not donate blood during treatment with isotretinoin and for one month after stopping treatment due to the possible risk to the fetus if the blood is transfused to a pregnant woman.
If you have any questions or concerns about taking isotretinoin, talk to your doctor or pharmacist.
Read the package leaflet carefully before you start treatment.
<u>A woman or girl of childbearing potential</u>
I am aware that:
• Isotretinoin is teratogenic and must not be taken during pregnancy. If used during pregnancy, isotretinoin can seriously harm an unborn child.
• If I become pregnant or think I might be pregnant, I will immediately stop taking isotretinoin and contact my doctor.
• I must use at least one highly effective method of contraception (for example, an intrauterine device or implant) or use properly two effective methods of contraception that work in different ways (for example, oral contraceptive tablets together with a condom) before and during treatment and for at least 1 month after stopping treatment.
• I must not become pregnant during treatment with isotretinoin and for 1 month after stopping treatment. • I must attend regular follow-up visits and have pregnancy testing (blood tests) at my doctor's office. • Before starting treatment, I must have a pregnancy test at my doctor's office which must be negative. • To make sure I am not pregnant during treatment, I must have regular pregnancy testing at my doctor's office for the duration of the treatment, ideally once a month. I must have my final pregnancy test 1 month after stopping treatment.
<u>What you must do if you are a woman or girl of childbearing potential*:</u>
• Use at least 1 very reliable method of contraception (such as an intra-uterine device or an implant) or correctly use 2 effective methods that work in different ways (such as an oral contraceptive together with a condom) for 1 month before taking Isotretinoin, during treatment and for one month after stopping treatment. • Do not become pregnant while taking Isotretinoin, or for 1 month after stopping treatment. • Attend regular follow-up visits and have regular pregnancy testing (blood tests):

- Before you start treatment, you will have to have a pregnancy test, which must be negative.
- To make sure you are not pregnant during treatment, you will have to take regular pregnancy tests, ideally every month.
- 1 month after stopping treatment, you will have to take a final pregnancy test.

*This applies to all girls and women using Isotretinoin and who could become pregnant.