

Pregnancy risks

- **YOU MUST NOT** take isotretinoin during pregnancy or if you are planning to get pregnant.
- Exposure to isotretinoin can seriously harm an unborn baby.
- **You must avoid becoming pregnant in the month before starting isotretinoin treatment, while taking isotretinoin and for 1 month after stopping treatment.**
- If you may be able to get pregnant, you must use effective contraception during this time. Talk to your prescriber to make sure you are using the right kind of contraception.
- If you have unprotected sex, you must get emergency contraception (morning-after pill or have an

Intrauterine device (IUD) fitted) as soon as possible. The pill must be taken within 3–5 days of unprotected sex and the IUD up to 5 days after unprotected sex or up to 5 days after the earliest time you could have ovulated.

- If you miss your period, become pregnant or think you might be pregnant, stop taking isotretinoin immediately, contact your dermatology team and seek medical advice. This applies during isotretinoin treatment and for 1 month after stopping.
- If there is any chance you could get pregnant, you must have regular pregnancy testing as instructed by your dermatology team.

Patient Reminder Card:
September 2026

Patient Reminder

Card for Isotretam (Isotretinoin)

You have been given this card because you have been prescribed Isotretam (isotretinoin) 10mg, 20mg & 40 mg S.G. Capsules and you need to know the possible side effects.



Medizen Pharmaceutical Industries-
Pharmacovigilance directorate Address- 426
El-Horreya Avenue, Roushdy, Alexandria

Tel: 03-5410722 / 01225659000
E-mail: medizen.pv@gmail.com
Online-reporting:
<https://forms.gle/RBtKj5SWruxwRZwdA>

Please read this card and the patient information leaflet thoroughly before starting your treatment with isotretinoin to ensure that you understand the range of side-effects associated with taking isotretinoin.

Please refer to the Patient Information Leaflet (PIL) for Isotretam for more information, which is available at the product package. And EDA website: www.edaegypt.gov.eg/

Contact details (names and number of the dermatology team)

See next page for advice on mental health contacts.

Important Reminders for Patients

DO NOT share this medicine with anybody. Return any unused capsules back to the pharmacy.

You MUST attend clinic appointments during treatment for regular monitoring and care.

Mental health: Talk to your dermatology team or GP about your treatment or if you have any concerns.

- You should stop taking isotretinoin and contact your dermatology team or GP for further advice if you have serious concerns about your mental health or thoughts of harming yourself or other serious side effects.
- Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit risk balance of the medicinal product.
- Please remember that any suspected adverse events should be reported to PVGA.

- The General Administration for pharmaceutical vigilance is reminding HCP and public to report any safety information regarding human medicinal products including adverse drug reactions, medications errors, lack of efficacy and other medicine related problems through the following contacts:

Name: General Administration for Pharmaceutical Vigilance
Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, PO box: 11451
Telephone: (+2)02 25354100, Extension: 1470
Fax: +202-23610497
Email: pv.followup@edaegypt.gov.eg Online reporting: <https://vigiflow-eforms.who-umc.org/eg/med>
(Patients & Healthcare providers)



- If you have seriously harmed yourself or think you may do so, call 16328 or go to <https://mentalhealth.mohp.gov.eg/>
- **You must NOT** donate blood during treatment with this medicine and for 1 month after stopping.

If you have any questions or concerns about taking isotretinoin, talk to your dermatology team or GP.