

Pharmacist Checklist

Guidance for Dispensing Oral Isotretinoin (Isotretam Soft Gelatin Capsule)



Isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to isotretinoin, even for short periods of time, presents a high risk of congenital malformations and miscarriage.

Therefore, isotretinoin is strictly contraindicated during pregnancy.

People with childbearing potential must fulfil the conditions of the isotretinoin Pregnancy Prevention Programme (PPP). Contraception is required unless the prescriber and patient agree they expect no risk of pregnancy during treatment and 1 month after treatment.

A person has childbearing potential if they have a uterus **and** at least one ovary unless they:

- Have undergone surgical sterilisation (tubal ligation), confirmed by a healthcare professional.
- Are post-menopausal, confirmed by a healthcare professional.

All patients with childbearing potential (anyone who may be able to get pregnant) must be entered into the Pregnancy Prevention Programme.

A person with childbearing potential requires contraception 4 weeks before treatment, during treatment and 1 month after, **UNLESS** the prescriber and patient agree that, during treatment and for 1 month after treatment, there is **no expected risk of pregnancy** due to:

- Only having sex/sexual intercourse with a person who has no potential to make them pregnant. This must be for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment. Ex. (Person who has had a vasectomy with two confirmed tests of being sperm-free).
- Long-term sexual abstinence (no sexual activity) for the duration of isotretinoin and for 1 month after stopping isotretinoin treatment.

Applicability of the Pregnancy Prevention Programme to the patient's circumstances **should be confirmed at each clinic visit by the healthcare professional and should be recorded on the prescription** as one of the following:

PPP not applicable - no childbearing potential	No requirement for pregnancy testing. Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring required) once patient is stable on treatment.
PPP group A - no expected risk of pregnancy (see above)	Pregnancy testing not mandated. Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring required) once patient is stable on treatment.
PPP Group B - on highly effective contraception (IUD, IUS or implant) for at least 4 weeks	Pregnancy testing will be done at clinic appointments and patients are advised they may wish to do monthly pregnancy tests at home because no contraceptive is 100% effective. Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring required) once patient is stable on treatment.
PPP Group C - on effective contraception (a hormonal contraceptive pill or hormonal injection PLUS a barrier method i.e. condom, female condom or vaginal cap) for at least 4 weeks	Pregnancy testing is mandated monthly prior to issue of prescription. Prescription will be limited to 30 days and will need to be picked up within 7 days of the pregnancy test and prescription being issued.

If you are aware that a pregnancy has occurred in a patient treated with isotretinoin or within 1 month of stopping isotretinoin, treatment should be stopped immediately, and the patient should be referred promptly to the prescribing healthcare professional.

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As a pharmacist, you should only dispense isotretinoin AFTER checking the following information:

For patients of childbearing potential:

Has the PPP status of the patient been recorded on the prescription?
What is the prescription length?
Is there a confirmed pregnancy test result, if applicable?

All patients should be instructed:

Never to give their 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 1 month after discontinuation due to the potential risks to the foetus of a pregnant transfusion recipient.

To talk to their dermatology team or GP about their treatment if they have any concerns. To stop taking isotretinoin and contact their dermatology team or GP for further advice if they have serious concerns about their mental health or thoughts of harming themselves or other serious side effects.

If they have seriously harmed themselves or feel that they may be about to harm themselves, call 16328 or go to <https://mentalhealth.mohip.gov.eg/>

Report any suspected adverse reactions. More Information about the Isotretinoin pregnancy and fetal exposure prevention program, as well as orders for additional copies of the risk minimization materials for the prevention program:

www.medizenegypt.net

Call For reporting:

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 (PVGA)

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>

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QR Code:

(Patients & Healthcare providers)



And / Or:

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

Tel: 03-5410722 / 01225659000

E-mail: medizen.pv@gmail.com

Medizen Online reporting : <https://forms.gle/RBtKj5SWruxwRZwdA>

You must check the patient has been given a Patient Reminder Card. Please encourage them to read this, and the package information leaflet thoroughly before and during treatment with isotretinoin.