Pharmacist Checklist Guidance for Dispensing Oral Isotretinoin ▼

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:

- a) Have undergone surgical sterilisation (tubal ligation), confirmed by a healthcare professional.
- b) 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:

- a) 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. Examples include sex with a:
 - Person of the same-sex
 - Person who has had a vasectomy with two confirmed tests of being sperm-free
 - Transgender man
- b) 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.

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.

They can also call the NHS on 111 or local mental health crisis team, for support out of hours. Alternatively, they can call the Samaritans to talk about anything that is upsetting them, 24 hours a day, 365 days a year. They can call 116 123 (free from any phone).

If they have seriously harmed themselves or feel that they may be about to harm themselves, call 999 for an ambulance or go straight to A&E.

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.

▼This medicinal product is subject to additional monitoring.

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to the MHRA and the company listed in the patient's package information leaflet, who will follow up with you to record the pregnancy outcome.

Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported to the MHRA, and the company listed in the patient's package information leaflet. Reporting forms and information can be found at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

To order further hard copies of the Oral Isotretinoin PPP materials please email: <u>oralisotretinoinppp@linney.com</u> or call: 0370 703 0602 Electronic copies are available at: <u>www.medicines.org.uk/emc</u>