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.

Isotretinoin is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions in the Isotretinoin Pregnancy Prevention Programme are fulfilled.

A negative pregnancy test, issuing a prescription and dispensing Isotretinoin should ideally occur on the same day

If you are aware that a pregnancy has occurred in a woman treated with Isotretinoin, treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within one month of stopping Isotretinoin she should be referred to her prescribing doctor.

As Pharmacist, you should only dispense Isotretinoin after checking the following information:

For women of child-bearing potential:
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for Isotretinoin should ideally be limited to a 30-day supply.
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 one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.
You must check the patient has been given a Patient Reminder Card. Please encourage them to read it 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 Malta Medicines Authority and the company listed in the patient's package information leaflet.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to the Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 : postlicensing.medicinesauthority@gov.mt

Alternatively you may report suspected adverse drug reactions to the Marketing Authorisation Holder at Ennogen Healthcare Ltd, Unit G4, Riverside Industrial estate, Riverside Way, Dartford, DA1 5BS, UK. Email address: info@ennogen.com

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Medicines Authority approval date: 24th January 2022.