Pharmacist Checklist - Guidance for dispensing Isotretinoin Rowex▼ (isotretinoin)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See box below for details on how to report.

Isotretinoin Rowex belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Isotretinoin Rowex, even for short periods of time, presents a high risk of very severe and serious congenital malformations and an increased risk of spontaneous abortion. **Isotretinoin Rowex is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions of the Isotretinoin Rowex Pregnancy Prevention Programme are fulfilled.** If you are aware that a pregnancy has occurred in a woman treated with Isotretinoin Rowex, 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 Rowex she should be referred to her prescribing doctor.

Patient Reminder Card

Counsel all patients (male and female) on the patient reminder card which is included in the product packaging. In the event that broken bulk dispensing cannot be avoided, the patient should be provided with a copy of the package leaflet and the patient reminder card.

As a pharmacist, you should only dispense Isotretinoin Rowex after checking the following information:

This material is provided by Rowex Limited as a licence requirement for this medicine and forms part of the Isotretinoin Rowex Risk Management Plan.
This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See box below for details on how to report.

For women of child-bearing potential:

In order to support regular follow up, including pregnancy testing and monitoring, the prescription for Isotretinoin Rowex should ideally be limited to a 30-day supply.	☐
Ideally, pregnancy testing, issuing a prescription and dispensing of Isotretinoin Rowex should occur on the same day.	☐
Dispensing of Isotretinoin Rowex should occur within a maximum of 7 days of the prescription.	☐

All patients should be instructed:

Never to give the Isotretinoin Rowex to another person.	☐
To return any unused capsules to their pharmacist at the end of treatment.	☐
Not to donate blood during Isotretinoin Rowex therapy and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	☐

Reporting of suspected adverse events or reactions

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; P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann or E: postlicensing.medicinesauthority@gov.mt

Further Information

For additional electronic copies of this risk minimisation material, refer to https://medicinesauthority.gov.mt/rmm and download the required material