FOR USE IN IRELAND

Pharmacist Checklist – Guidance for dispensing Roaccutane® (isotretinoin)

This material is provided by CHEPLAPHARM Registration GmbH as a licence requirement for this medicine and forms part of the Roaccutane® Risk Management Plan

Roaccutane® belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to Roaccutane®, even for short periods of time, presents a high risk of very severe and serious congenital malformations and an increased risk of spontaneous abortion. **Roaccutane® is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions of the Roaccutane® Pregnancy Prevention Programme are fulfilled.** If you are aware that a pregnancy has occurred in a woman treated with Roaccutane®, 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 Roaccutane® 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 Roaccutane® 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 Roaccutane® should ideally be limited to a 30-day supply.	☐
Ideally, pregnancy testing, issuing a prescription and dispensing of Roaccutane® should occur on the same day.	☐
Dispensing of Roaccutane® should occur within a maximum of 7 days of the prescription.	☐

All patients should be instructed:

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

For further information, please refer to the Roaccutane Summary of Product Characteristics available at www.hpra.ie

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Reporting of suspected adverse events or reactions

Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions (see details below).

In the event of a suspected adverse event, please report it to:
Red Line Pharmacovigilance Ltd
Challenge House, Sherwood Drive, Bletchley, Milton Keynes, MK3 6DP, United Kingdom
Email: cheplapharm@redlinepv.co.uk
Telephone: +353 1800 123 000

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
The Health Products Regulatory Authority
Website: www.hpra.ie

Further Information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Roaccutane' or 'isotretinoin' in the search box and click on 'EdM' next to any of the medicines that appear). Alternatively if you would like hard copies, please contact cheplapharm@redlinepv.co.uk

For further information about Roaccutane®, please contact Red Line Pharmacovigilance Ltd, Challenge House, Sherwood Drive, Bletchley, Milton Keynes, MK3 6DP, United Kingdom.
Tel: +353 1800 123 000; Email: cheplapharm@redlinepv.co.uk

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