

Important Safety Information

Pharmacist Checklist - Guidance for dispensing Roaccutane®

Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported. Reporting forms and information can be found at:

ABDULREHMAN ALGOSAIBI G.T.C

Email: safety@aralgosaibico.com

Tel: +966 11 4793000

Mobile: +966 58 016 0683

Or:

The National Pharmacovigilance Centre (NPC) at the Saudi Food and Drug Authority (SFDA)

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa/>



Roaccutane®
Isotretinoin

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Isotretinoin belongs to the retinoid class of drugs that cause severe birth defects. Fetal 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 Roaccutane® 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.

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All patients should be instructed:

Never to give Isotretinoin to another person.

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To return any unused capsules to their pharmacist at the end of treatment.

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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.

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To talk to their dermatologist about their treatment if they have any concerns.

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To stop taking isotretinoin and contact their dermatologist for further advice if they have serious concerns about their mental health or thoughts of harming themselves or other serious side effects.

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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.

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