

PHARMACIST CHECKLIST Guidance for dispensing Ruatine® (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.

Call for reporting

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported.

■ Cigalah Group

Sharafiyyah District - Al Yousfia Building

P.O. Box 19435 - Ali Bin Abi Taleb Street, Jeddah, 21435 Saudi Arabia Tel: +966-12-6148259 - Mob: +966-539455825 - Fax: +966-12-6148458

Email: drug-safety@cigalah.com.sa - moghamdi@cigalah.com.sa

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

SFDA call center: 19999

Toll free phone: 8002490000 - Fax: +966-11-2057662

E-mail: npc.drug@sfda.gov.sa - Website: http://ade.sfda.gov.sa/

Ruatine® Leaflet