

# Pharmacist Checklist

## Guidance for Dispensing Ruatine<sup>®</sup> (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.

**Therefore, Isotretinoin is strictly contraindicated during pregnancy.**

**People with childbearing potential must fulfill the conditions of the Isotretinoin Pregnancy Prevention Programme (PPP). Contraception is required unless the prescriber and patient agree they expect no risk of pregnancy during treatment and 1 month after treatment.**

Female with childbearing potential unless they:

- a. Have undergone surgical sterilization (tubal ligation), confirmed by a healthcare professional.
- b. Are post-menopausal, confirmed by a healthcare professional.

All patients with childbearing potential (anyone who may be able to get pregnant) must be entered into the Pregnancy Prevention Programme.

A person with childbearing potential requires contraception 4 weeks before treatment, during treatment, and 1 month after, **UNLESS** the prescriber and patient agree that, during treatment and for 1 month after treatment.

Applicability of the Pregnancy Prevention Programme to the patient's circumstances **should be confirmed at each clinic visit by the healthcare professional** and **should be recorded on the Acknowledgement of Risk Form** as one of the following:

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|---|---|
| <b>PPP not applicable</b> - no childbearing potential   | No requirement for pregnancy testing.<br>Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring is required) once the patient is stable on treatment.  |
| <b>PPP group A</b>  | Pregnancy testing is not mandated.<br>Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring is required) once the patient is stable on treatment.   |
| <b>PPP Group B</b> - on highly effective contraception (IUD, IUS, or implant) for at least 4 weeks  | Pregnancy testing will be done at clinic appointments, and patients are advised they may wish to do monthly pregnancy tests at home because no contraceptive is 100% effective. Prescription may be extended for longer than 30 days (up to 12 weeks if no other side effect monitoring is required) once the patient is stable on treatment. |
| <b>PPP Group C</b> - on effective contraception (a hormonal contraceptive pill or hormonal injection PLUS a barrier method i.e. condom, female condom, or vaginal cap) for at least 4 weeks | Pregnancy testing is mandated monthly prior to the issue of prescription.<br>Prescription will be limited to 30 days and will need to be picked up within 7 days of the pregnancy test and prescription being issued.   |

If you are aware that a pregnancy has occurred in a patient treated with isotretinoin or within 1 month of stopping isotretinoin, treatment should be stopped immediately, and the patient should be referred promptly to the prescribing healthcare professional.

**As a pharmacist, you should only dispense isotretinoin AFTER checking the following information:**

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| <b>For patients of childbearing potential:</b>   |
| Has the PPP status of the patient been recorded in the Acknowledgement of Risk Form?<br>What is the prescription length?<br>Is there a confirmed pregnancy test result, if applicable?   |
| <b>All patients should be instructed:</b>  |
| <b>Never</b> to give their isotretinoin to another person.   |
| Any Ruatine® soft capsules unused after the end of treatment or by the expiry date must be returned in their original packaging to the place of supply (physician or pharmacist) for proper disposal   |
| Not to donate blood during isotretinoin therapy and for 1 month after discontinuation due to the potential risks to the foetus of a pregnant transfusion recipient.  |
| To talk to their dermatologist about their treatment if they have any concerns.<br>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. |
| <b>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.</b>  |

Pregnancies occurring during treatment and within 1 month following discontinuation of treatment should be reported to follow up and record the pregnancy outcome. For further information, refer to SPC or PIL .

### **Call For Reporting:**

**Any suspected adverse reactions should be reported immediately to MS Pharma Saudi or to the National Pharmacovigilance and Drug Safety Centre.**

- **Pharmacovigilance department at MS Pharma:**
  - Email: [pharmacovigilance@mspharma.com](mailto:pharmacovigilance@mspharma.com)
  - Website: [www.mspharma.com](http://www.mspharma.com)
  - Phone No: + 966112790122 Ext. 6013
- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
  - Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)
  - Call Center: 19999
  - Website: <https://ade.sfda.gov.sa/>
  - QR Code

