This document is approved by The Executive Directorate of Pharmacovigilance at SFDA

Direct Healthcare Professional Communication (DHPC)

Dear Healthcare provider,

MS Pharma in Agreement with the Saudi Food and Drug Administration (SFDA) would like to inform you of the following:

Summary

- All patients must be counselled about the benefits and risks of treatment before Ruatine® (Isotretinoin) is prescribed, including possible side effects relating to mental health and sexual function.
- Patients should also be monitored for these and other side effects during Isotretinoin treatment.
- New risk minimization materials have been developed to incorporate these new safety measures and support healthcare professionals and patients, as well as highlight the updates to the product information.
- The Acknowledgement of Risk Form is available for prescribers and should be completed with all patients. Patients should be provided with a copy of this as well as the Patient Reminder Card. A Pharmacist Checklist should be used by pharmacists as a reminder when dispensing Ruatine® (Isotretinoin).
- Applicability of the updated Pregnancy Prevention Programme must be assessed for all patients. Isotretinoin is contraindicated in women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met.

Changes to the product information

The product information (Ruatine® (Isotretinoin) Summary of Product Characteristics and Patient Information Leaflet) has been updated to:

- Highlight that all patients must be counselled about the benefits and risks of treatment before Isotretinoin is prescribed, including possible side effects relating to mental health and sexual function.
- Emphasise that patients should also be monitored for these side effects during isotretinoin treatment.

Updated risk minimization materials

Updated risk minimization materials have been created to incorporate these new safety measures and support healthcare professionals and patients, as well as highlight the updates to the product information. These materials apply to all patients and include:

1. Acknowledgement of Risk Form
2. Patient Reminder Card
3. Pharmacist Checklist

The Acknowledgement of Risk Form should be completed by the **prescriber** (to confirm that they have explained the risks of treatment) and by the **patient** (to confirm they have understood these risks and the associated actions required). A copy of the completed Acknowledgement of Risk Form should be given to the patient by the prescriber, along with the Patient Reminder Card. **Pharmacists** should ensure the Pharmacist Checklist is suitably placed as a reminder each time a Ruatine® (Isotretinoin) prescription is dispensed.

Applicability of the updated Pregnancy Prevention Programme must be assessed for all patients. Isotretinoin is contraindicated in women of childbearing potential unless all of the conditions of the Pregnancy Prevention Programme are met.

Call For Reporting:

▼ **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 below for how to report side effects.**

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- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
  - Email: npc.drug@sfda.gov.sa
  - Call Center: 19999
  - Website: https://ade.sfda.gov.sa/
  - QR Code: