

Healthcare Provider Guide To Prescribing Isotretinoin Containing Medications:

Isotretinoin containing medicines available in Saudi Arabia as soft capsules in the following trade names:

- Roaccutane®
- Xeractan®
- Curacne®

IMPORTANT NOTES:

Isotretinoin should only be prescribed by or under the supervision of physicians with expertise in the use of systemic retinoid for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements.

Oral Isotretinoin should only be prescribed in severe forms of acne (i.e. nodular and conglobata or acne at risk of permanent scarring), resistant to adequate courses of standard therapy with systemic antibacterial and topical therapy.

This Drug requiring a specific monitoring during treatment.

ISOTRETINOIN IS A TERATOGENIC DRUG:

Exposure to Isotretinoin during pregnancy is associated with a *high risk of major fetal malformations*. Isotretinoin can be prescribed to women of childbearing potential under strict pregnancy prevention measures.

TERATOGENICITY AND DRUG EXPOSURE DURING PREGNANCY:

Oral isotretinoin is subject to a Pregnancy



Prevention Program to make all parties involved (doctors, pharmacists and patients) aware of the teratogenic adverse effect of isotretinoin.

IN ADDITION TO TERATOGENICITY, ISOTRETINOIN CAN CAUSE SERIOUS ADVERSE EVENTS:

- Psychiatric disorders: To improve awareness of prescribers and patients regarding the risk of occurrence of psychiatric disorders during the treatment.
- Lipid disorders.
- Transaminases increased and hepatitis.

To remind the prescriber about the mandatory biologic monitoring.

FOR WOMEN OF CHILDBEARING AGE, THE FOLLOWING SHOULD BE PROVIDED BEFORE PRESCRIBING ORAL ISOTRETINOIN:

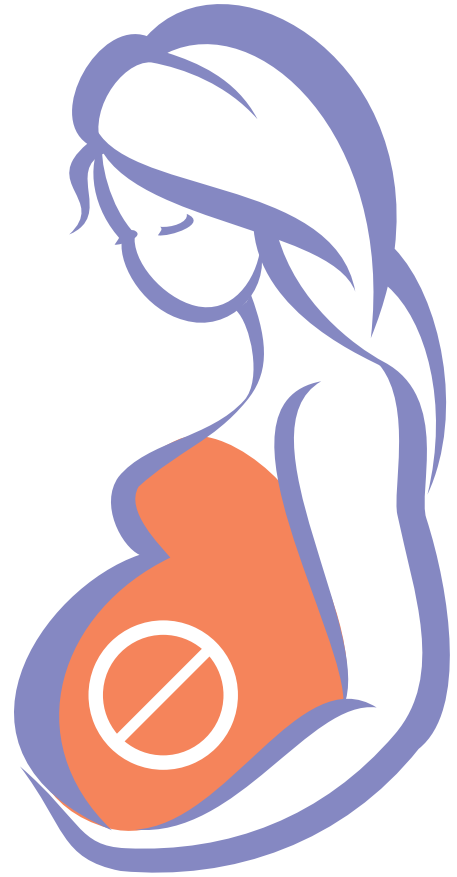
1. Contraception consent form
2. Patient Booklet.
3. Contraception Information Brochure for Isotretinoin Patients.

IF YOU ARE PRESCRIBING ORAL ISOTRETINOIN FOR FIRST TIME:

- The prescriber should evaluate the patient's level of understanding.
- The prescriber **must ensure** that the patient is using two methods of effective contraception (a barrier device is relevant as second method of contraception) for **at least 4 weeks prior to the start** of treatment and is able to continue the use of an effective contraception method throughout the treatment period and for **at least 4 weeks after cessation** of treatment.
- Negative pregnancy test results have been obtained **before, during and 5 weeks after** the end of treatment. The dates and results of pregnancy tests should be documented.
- Signing the patient on the consent form.
- **Prescription is limited to 4 weeks of treatment (one pack)**, if treatment continuation needed, a new prescription subordinated by a negative pregnancy test.

IN CASE OF MONTHLY RENEWAL:

- Make sure of the continuation of an effective contraception.
- Evaluate the patient's level of understanding of the teratogenic risk.
- Negative pregnancy test is required for prescription renewal.
- Verify the negative result of the pregnancy test.
- The same instructions applied for the first time treatment should be considered.



AT THE END OF THE TREATMENT:

- Remind your female patient that she must continue to use two methods of effective contraception (a barrier device is relevant as second method of contraception) for at least 4 weeks after stopping treatment with oral Isotretinoin.
- A final pregnancy test has to be done 5 weeks after stopping treatment. Verify the negative result of this test.

If a pregnancy occurs in a woman treated with oral Isotretinoin, the treatment must be stopped immediately and the patient should be referred to a physician specialized or experienced in teratogenicity for evaluation and advice.