

Subject: Direct Healthcare professional communication on the ideal use of Isotretinoin in management of acne.

Dear Healthcare professional,

Jazeera Pharmaceutical Industries would like to provide you with latest regulations with respect to Xeractan (**Isotretinoin**) use. Vigilance and crisis management executive directorate at Saudi Food and Drug Authority (SFDA) along with the Pharmacovigilance advisory committee are preparing an awareness campaign to control Isotretinoin usage by patients.

Isotretinoin is teratogenic, classified as Category X, and known to cause birth defects to the fetus, the use of Isotretinoin is contraindicated in pregnancy or where there is a possibility of pregnancy.

The female patient should be aware of all the risks associated with Isotretinoin during the treatment period and four weeks after the end of the treatment.

Accordingly, the SFDA suggested some recommendation to control Isotretinoin use.

The SFDA requested the Isotretinoin manufacturers to provide a medication guide that contains important safety advises about Isotretinoin, and a consent form which will be signed by the patient once he/she has received the treatment.

Prescribers are advised to adhere to the following points in order to get the best result out of this awareness campaign:

- 1- Prescribers should give the medication guide to all patients.
- 2- Prescribers should explain & review the teratogenicity of Isotretinoin with the female patients.
- 3- Prescriber should inform the patient to sign on a consent form in the pharmacy to receive the treatment.

JPI would like to keep you assured that the patient's safety is a top priority. We are committed to continuously monitor the safety and tolerability of our products throughout ensuring effective and well-established Pharmacovigilance system and to keep close communication with SFDA as well as healthcare providers to update them with most recent safety data about any potential risks associated with the use of Isotretinoin.

Call for reporting

You can assist us by reporting to:

- JPI Al Jazeera Pharmaceutical Industries
 - E-mail: medical@jpi.com.sa.
 - Fax: + 966 1 2078097

- SFDA (Saudi Food and Drug Authority – National Pharmacovigilance and Drug safety center)
 - E-mail to: npc.drug@sfd.sa
 - Fax :+966 1 2057662