The second version of risk minimization measures for birth defects associated with isotretinoin-containing products use in pregnant women

The Saudi Food and Drug Authority (SFDA) would like to remind the healthcare professionals (HCPs) of the recent approved risk minimization measures that aims to mitigate the risk of birth defects associated with the use of isotretinoin-containing products by increasing awareness and educating healthcare provider as well as the patients about the serious adverse drug reactions, particularly teratogenicity.

Isotretinoin, used for the treatment of severe forms of acne, is known to cause some serious birth defects if used during or prior to gestational period. The National Pharmacovigilance and drug safety Center (NPC) in collaboration with the manufacturers of isotretinoin-containing products has approved the pregnancy prevention program that aims to minimize the risk of teratogenicity associated with the use of isotretinoin-containing products by female patients who are or might become pregnant. The program consists of medication guide for patients and medical consent form. Click here for more details.

The SFDA urges the healthcare professionals to read these activities and use them to minimize the risk of fetal toxicity and teratogenicity associated with the use of isotretinoin-containing products in female patients who are or might become pregnant.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 01 2038222 ext. 2317-2356-2340.
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa