May 5th , 2013

The SFDA Revoked the Marketing Authorization of Ritodrine (YUTOPAR®) in Saudi Arabia.

On April 29 ,2013, the Saudi Food and Drug Authority (SFDA) announced that the marketing authorization of ritodrine (Yutopar®) was revoked in Saudi Arabia. The SFDA decision was based on reviewing of clinical trials, meta-analyses and in-vitro studies that indicated that the risk of serious adverse events is significantly increased among users of ritodrine. Ritodrine has a direct relaxant effect on the smooth-muscle fibers of the myometrium and was used to suppress preterm labour.

The National Pharmacovigilance and Safety Centre has reviewed the safety and efficacy profiles of Yutopar® and has concluded that the risks associated with the use of this drug outweigh its benefits. In addition, it has been found that ritodrine is associated with several serious adverse effects such as Respiratory Distress Syndrome (RDS), fatal tachycardia and dyspnea. The Pharmacovigilance Advisory Committee also confirmed the unfavourable risk-benefit balance of Yutopar®. Therefore, the SFDA advices healthcare professionals that Yutopar® is no longer approved in Saudi Arabia and they should discuss with their patients the available alternatives.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using such a medication and other 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: 8002490000
Tel: 012038222 ext. 2354, 2317,2340
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa