



SFDA SAFETY COMMUNICATION

27/06/2016

Saudi Food and Drug Authority (SFDA) –Ribavirin and Risk of Birth Defect

Saudi Food & Drug Authority (SFDA) would like to remind health care professionals (HCPs) that the use of ribavirin during pregnancy might cause severe birth defects or even abortions.

The summary of product characteristics (SPC) and patient information leaflet (PIL) of this product were amended to include that the use of ribavirin therapy is contraindicated in women who are pregnant and in the male partners of women who are pregnant. In addition, a pregnancy prevention instructions and periodic pregnancy testing were clearly addressed.

On 2016, the National Pharmacovigilance Center (NPC) received a local spontaneous case made by a HCP of a male patient receiving ribavirin therapy for chronic hepatitis C and his wife recently found out that she is pregnant. Therefore, the SFDA emphasizes that HCPs should instruct their patients that ribavirin must not be used by pregnant women or by male partners of pregnant women. Women and their male partners should avoid pregnancy, using two effective forms of birth control, while taking ribavirin and for additional six months after stopping the treatment.

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, 5769
Fax: 01 2057662
Email: NPC.Drug@sfd.gov.sa