SFDA SAFTEY COMMUNICATION

Feb 5th , 2013

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Safety of Diane 35® and Risk of Thromboembolism

The Saudi Food and Drug Authority (SFDA) would like to share some recent information regarding use of Diane 35® (cyproterone acetate 2 mg + ethinyl estradiol 35 micrograms). On 30/01/2013, the French medicines agency (ANSM) announced that they decided to suspend the marketing authorisation for Diane 35® and its generics for acne treatment in France within three months. This decision was based on review of known data by the French medicines agency. The agency found that Diane 35® and its generics carry a risk of thromboembolism, while their effectiveness in treating acne is moderate and there are other available alternatives. Moreover, Diane 35® was widely used off-label as a contraceptive in France.

In Saudi Arabia, Diane-35® is used in cases of androgenization symptoms in women requiring hormonal treatment such as acne, hirsutism and androgenetic alopecia. Also, Diane-35® is used as contraceptive in women who have androgen-dependent clinical symptoms.

SFDA is currently reviewing the safety profile of Diane 35® to assess the benefit-risk balance and it will release the results of this review when it finished.

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
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa