



May 27th , 2013

Saudi Food and Drug Authority (SFDA) Second Press Release- Safety of Diane- 35® (Ethinylestradiol/Cyproterone) and Risk of Thromboembolism

The Saudi Food and Drug Authority would like to inform healthcare providers that following the safety review of Diane-35® (Ethinylestradiol/Cyproterone), it has been found that the drug's benefits continue to outweigh the risks, provided that:

1. The use of Diane-35® is restricted to treatment of androgenization symptoms (symptoms caused by an increased effect of male sexual hormones) including hirsutism and moderate to severe acne, refractory to topical and oral antibiotic therapy.
2. The drug **SHOULD NOT** be used as a contraceptive in women who do not suffer from androgen-dependent conditions.
3. Diane-35® is a hormonal contraceptive. Women should not use it in combination with other hormonal contraceptives, as this will increase the dose of estrogen and as a result, a higher chance of developing thromboembolism.

Report Adverse Drug Events (ADEs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADEs 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: 0112038222 ext. 2354, 2317,2340 , 2356

Fax: 0112057662

Email: NPC.Drug@sfd.gov.sa