Bayer HealthCare
Bayer Pharmaceuticals
P.O. Box 16207
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Saudi Arabia

22 JUL 2013

The Use of Diane-35® (Ethinylestradiol / Cyproterone) and Risk of Thromboembolism

Dear Healthcare Professional,

Bayer would like to inform you of the outcome of a review of the known risk of thromboembolic events and benefits of medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms . The evaluation has been performed by the Saudi Food and Drug Authority (SFDA) following concerns about the risk of venous and arterial thromboembolism (VTE and ATE) associated with those products.

Summary

The SFDA recommendations include:

- The use of Diane-35® must be restricted to treatment of androgenization symptoms (symptoms caused by increased effect of male sexual hormones) including hirsutism and moderate to serve acne, refractory to topical and oral antibiotic therapy.
- The drug SHOULD NOT be used as a contraceptive in women who do not suffer from androgen-dependent conditions.
- 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.
- To increase awareness of the risk and risk factors of thromboembolism in relation to the use of Diane 35® (e.g. increasing age, smoking, immobility), the warnings and precautions regarding this risk have been strengthened.

Further information on the safety concern and the recommendations

The SFDA assessed all available data on the risk of thromboembolism as well as the benefits of medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 mcg including the published literature.

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The SFDA concludes that the risk of VTE and ATE is increased in users of medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms.

It is important that healthcare professionals and women using medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 micrograms are aware of the risk of VTE in order to prevent complications and fatal outcomes and to facilitate a timely and correct diagnosis of VTE. Therefore educational material for prescribers and patients will be distributed.

This information has been agreed with the SFDA

Call for reporting

Bayer encourages you to report any adverse reaction, including possible thromboembolic or cardiac events, which may be associated with the use of Diane 35 according to national procedures.

The National Pharmacovigilance and Drug Safety Center
Email: npc.drug@sfda.gov.sa
Fax: +966112057662

Adverse reactions can also be reported to the address given below:

Dr. Khaled A. Halim, Medical Manager, Bayer Health Care, Saudi Arabia

Tel : + 96626571676 ext 2257

Fax : + 96626571085

Email: khaled.a-halim@bayer.com

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