European Medicines Agency starts safety review of Diane-35 and its generics

13.03.2013 | P06/2013

Information on Medicinal Product

- Diane-35 is a medicinal product used to treat women with severe acne that has not improved after treatment with oral antibiotics, to treat excessive growth of hair on the face or body (hirsutism).
- Diane-35 is not authorised in Malta. Clairette and Acnocin are two generics which are authorised in Malta, but only Clairette is marketed.
- Clairette 2000/35 tablets like Diane-35, contains the active ingredients cyproterone acetate and ethinylestradiol.
- Although Clairette 2000/35 can act as an oral contraceptive, it is not approved to be used in women solely for this purpose. Rather, it should only be used for contraception in women who require treatment for the skin conditions described above.
- In women, the ovaries have to make male sex hormones (androgens) which are then changed into female sex hormones (oestrogens). Androgens help the skin to grow but can also cause the over production of sebum (oil), leading to blockage of the oil glands which may then become infected and inflamed, resulting in acne spots. Androgens production may also increase the growth of facial and body hair.
- The active ingredients in Clairette 2000/35 tablets block the receptors by means of which androgens act and also reduce the amount of androgens available by cutting down its production.

Information from European Medicines Agency about the safety concern

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) formally started a safety review of Diane 35 and its generics at the request of the French medicines regulatory agency (ANSM), following the announcement of its plan to suspend the

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

marketing authorisations for Diane 35 and its generics for acne treatment in France over the next three months. This was the result of an analysis of known data, including reports of venous and

arterial thromboembolism (VTE and ATE, the formation of blood clots in the veins or arteries) recorded in the French national pharmacovigilance database in association with Diane 35 and its generics over a period of more than 20 years.

The risk of venous thromboembolism with these medicines is low but well known, and warnings are included in their product information to alert patients and prescribers to the risks. European legislation requires that there is a coordinated European approach when a Member State takes regulatory action in relation to a medicine that is authorised in more than one country. Therefore, the PRAC will evaluate all available evidence on the benefits and risks of these medicines and give a recommendation on whether their marketing authorisations should remain as they are, be varied, suspended or revoked, in the interest of all patients in the European Union.

In Malta

For Healthcare Professionals

- The Medicines Authority would like to advise prescribers to limit the use of Clairette to its authorised indications of treatment, that is, for use in women only for the treatment of (a) severe acne, refractory to prolonged oral antibiotic therapy; (b)moderately severe hirsutism.
- Further review of European data is necessary to evaluate the impact on the risk profile of cyproterone acetate and ethinylestradiol and the outcome of this review will be published on the Medicines Authority website when it is made available.

Advice for Patients

- The Medicines Authority advises patients who are currently taking Clairette not to stop its use abruptly, but to consult their doctor in case they have any concerns and to read the patient information leaflet.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

For more information please see the press release issued by the European Medicines Agency on www.ema.europa.eu .

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Clairette. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.>

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt