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Press Office

Press release

Benefits of Diane 35 and generics outweigh risks in specific patient group

PRAC recommends measures to minimise risks of thromboembolism

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that the benefits of Diane 35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms) and its generics outweigh the risks, provided that several measures are taken to minimise the risk of thromboembolism (formation of blood clots in the veins and arteries). These medicines should be used solely in the treatment of moderate to severe acne related to androgen-sensitivity and/or hirsutism (excessive unwanted growth of hair) in women of reproductive age. Furthermore, Diane 35 should only be used for the treatment of acne when alternative treatments, such as topical therapy and oral antibiotic treatment, have failed.

Since Diane 35 and its generics are hormonal contraceptives, women should not take these medicines in combination with other hormonal contraceptives. Concomitant use of Diane 35 and its generics with another hormonal contraceptive will expose women to a higher dose of estrogen and increase the risk of thromboembolism.

The PRAC recommendation will now be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

The risk of venous thromboembolism (VTE) occurring with these medicines is low and well known, and warnings are included in their product information to alert patients and prescribers to the risks.

The Europe-wide review was initiated at the request of the French medicines regulatory agency (ANSM), following the announcement of its plan to suspend the marketing authorisations for Diane 35 and its generics in France. This was the result of a national benefit/risk review by ANSM of the product. This review highlighted serious thromboembolic events and extensive off-label use of these medicines as a contraceptive only.

Based on all available data, the PRAC concluded that Diane 35 and its generics have a place as a treatment option for certain women suffering from the above-mentioned conditions. It also acknowledged that there is a need to take further measures to better address and minimise the risks of thromboembolism associated with these medicines.

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Risk-management activities

The PRAC recommended new contraindications and warnings to patients and healthcare professionals.

The PRAC also recommended that efforts should be made to raise awareness of the risks, signs and symptoms of thromboembolism, to allow for timely diagnosis and appropriate treatment. This includes educational materials for prescribers and patients highlighting the risks of thromboembolism, for example a prescriber checklist, to ensure that the risks, together with the signs and symptoms, are discussed.

The Committee also recommended further pharmacovigilance activities, including prospective drug-utilisation studies to assess future prescription patterns following the above-mentioned changes to the product information, as well as a post-approval safety study to assess the effectiveness of the risk-minimisation measures.

More on the review

These medicines have been authorised at the level of individual Member States for many years. They are widely used across Europe. However, their authorised uses at the time of this review differ between Member States.

During the review, the PRAC assessed all available data on the risk of thromboembolism with Diane 35 and its generics, based on post-marketing data in Europe and other published literature. The Agency also invited stakeholders, including healthcare professionals, patients' organisations and the general public, to submit data relevant to the procedure. Data were submitted by eight stakeholders and these were fed into the assessment. A group of experts including patient representation was also convened to provide advice to support the review.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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