



IRISH MEDICINES BOARD

DIANETTE (CYPROTERONE ACETATE 2MG /ETHINYLESTRADIOL 35MCG) – NEW RISK MINIMISATION MEASURES TO FURTHER MITIGATE THE KNOWN RISK OF THROMBOEMBOLISM

An EU review of Dianette (cyproterone acetate 2mg, ethinylestradiol 35 micrograms), which is a treatment for acne and other hormone related conditions, has concluded that the benefits continue to outweigh the risks, provided that a number of measures are taken to minimise the well known risk of thromboembolism.

This medicine should now be used solely in the treatment of moderate to severe acne related to androgen sensitivity or hirsutism in women of reproductive age. Furthermore, Dianette should only be used for the treatment of acne when alternative treatments, such as topical therapy and oral antibiotic treatment, have failed.

The progestogen content of Dianette (i.e. cyproterone acetate), suppresses ovulation and therefore also has a contraceptive effect, although it is not authorised as a contraceptive in its own right. Concomitant use of Dianette with another hormonal contraceptive will expose women to a higher dose of oestrogen and increase the risk of thromboembolism, therefore must not be taken in combination.

The risk of thromboembolism occurring with these medicines is low and well known. The review concluded that the risk of venous thromboembolism (VTE) and arterial thromboembolism (ATE) is increased in users of Dianette, with the excess risk of VTE being highest during the first year a woman starts treatment, or when restarting or switching after a pill-free interval of at least a month. There is evidence from epidemiological studies that the incidence of VTE is 1.5 to 2 times higher in users of Dianette than in users of levonorgestrel-containing combined hormonal contraceptives (CHCs) and may be similar to the risk for desogestrel, gestodene and drospirinone-containing CHCs.

To highlight awareness of this risk, new educational materials for healthcare professionals and patients have been developed and will be distributed by the company, in addition to a direct healthcare professional communication (DHPC).

Advice to Healthcare Professionals

- Dianette should now be used solely in the treatment of moderate to severe acne related to androgen sensitivity or hirsutism in women of reproductive age. For the treatment of acne, Dianette should only be used when alternative treatments, such as topical therapy or oral antibiotic treatment, have failed.
- Since Dianette is a hormonal contraceptive, women should not take this medicine in combination with other hormonal contraceptives.
- It is important that healthcare professionals and women using Dianette are aware of the risk of VTE in order to prevent complications and serious adverse outcomes and to facilitate a timely and correct diagnosis of VTE. Educational materials will also highlight risk factors for VTE including increasing age, smoking and immobility.

Key message

- New risk minimisation measures are being introduced to further mitigate the known risk of thromboembolism for Dianette, a treatment for acne and hirsutism containing cyproterone acetate 2mg, ethinylestradiol 35mcg.

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