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Start of review of medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg for acne

The European Medicines Agency (EMA) has started a review of medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg when used for acne.

These products are available in several countries in the European Union (EU) as oral contraceptives and for the treatment of moderate acne in women.

The review of these medicines has been requested by the UK's medicines agency (MHRA) because of concerns that the benefits of dienogest/ethinylestradiol have not been sufficiently demonstrated in the treatment of acne. The MHRA was also concerned about the risk of venous thromboembolism (VTE or blood clots in veins), which has not been sufficiently characterised for this combination, and noted that alternative treatment options for acne are available.

EMA will now review all available data on the benefits and risks of medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg in the treatment of acne, and will issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU. While the review is ongoing, women who have any questions should consult their doctor or pharmacist.

More about the medicines

Medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg are used as oral contraceptives and for the treatment of moderate acne in women when topical treatment is ineffective. They have been authorised as Valette and other trade names via national procedures in the following EU Member States: Austria, Belgium, Bulgaria, Czech Republic, Estonia, Germany, Hungary, Latvia, Lithuania, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia and Spain.

Dienogest and ethinylestradiol are two types of hormones, a progestogen and an oestrogen. They work by changing the body's hormonal balance.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

More about the procedure

The review of medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg for acne has been initiated at the request of the UK's medicines agency (the Medicines and Healthcare products Regulatory Agency, MHRA), under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's final opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.