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Dienogest/ethinylestradiol can be used for acne after certain other treatments have failed

Use should be limited to women who choose oral contraception

On 26 January 2016, the European Medicines Agency (EMA) recommended that medicines containing a combination of dienogest 2 mg and ethinylestradiol 0.03 mg can continue to be used to treat moderate acne when suitable treatments applied to the skin or antibiotics taken by mouth have not worked. However, these medicines, which are also approved as hormonal contraceptives, should only be used in women who choose oral contraception.

Having evaluated the existing data on the effectiveness of the combination in the treatment of acne, EMA's Committee for Medicinal Products for Human Use (CHMP) concluded that there is sufficient evidence to support its use in moderate acne. Regarding the risk of side effects, the CHMP considered that the available data do not raise any new safety concern. The known risk of venous thromboembolism (VTE or blood clots in veins), which can occur with all combined hormonal contraceptives, is considered low. However, the data on the risk with dienogest/ethinylestradiol are not sufficient to accurately estimate how it compares with other contraceptives and further data are still awaited.

Considering the observed benefits of dienogest/ethinylestradiol in the treatment of acne, the potential risk of VTE and the nature of the disease, the CHMP concluded that this combination should only be used after certain other treatments have failed, and only when oral contraception is chosen. The CHMP also recommended that women should be assessed by their doctor 3 to 6 months after starting treatment and periodically thereafter to review the need for continuation of treatment.

The prescribing information for these medicines will be updated in line with the above recommendations.

Information for patients

- Medicines containing dienogest and ethinylestradiol should only be used to treat moderate acne in women who also choose oral contraception. They should only be used when treatments applied to the skin or an antibiotic taken by mouth have not worked.
- You should be aware that, as with other hormonal contraceptives, there is a risk of blood clots associated with the use of dienogest/ethinylestradiol. While this risk is low, the data on the risk with dienogest/ethinylestradiol are still insufficient to accurately estimate how it compares with other contraceptives.

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- When taking dienogest/ethinylestradiol, you should be alert to the signs and symptoms of blood clots in veins, which may include severe pain or swelling in the legs, sudden unexplained breathlessness, rapid breathing or cough, chest pain, and weakness or numbness of the face, arms or legs. If you develop any of these signs and symptoms you should seek medical advice immediately.
- Your acne will usually improve after 3 to 6 months of treatment with dienogest/ethinylestradiol. Your doctor will assess whether you should continue treatment with this medicine 3 to 6 months after you have started treatment and regularly after that.
- If you have any questions or concerns, speak with your doctor, pharmacist or nurse.

Information for healthcare professionals

- The combination dienogest/ethinylestradiol should be used for the treatment of moderate acne only after failure of suitable local therapies or oral antibiotic treatment in women who elect to use an oral contraceptive.
- Data from two phase III trials (study no. A07062 and A28501) in a total of around 2,400 women (mostly with moderate acne) showed that dienogest/ethinylestradiol was more effective than placebo and at least as effective as ethinylestradiol/norgestimate and ethinylestradiol/cyproterone at treating acne in terms of changes in inflammatory lesion count, total lesion count and improvement of facial acne according to IGA (Investigator's Global Assessment).
- It is not known how the efficacy of dienogest/ethinylestradiol compares with other acne treatments, i.e. topical treatments and systemic antibiotics.
- The currently available safety data do not raise any new safety concerns. However, to date, there are insufficient data to accurately determine the relative risk of venous thromboembolism (VTE) with respect to other combined hormonal contraceptives containing other progestogens.
- Taking into account the available evidence, and in order not to unnecessarily expose women to a potentially higher risk of VTE, use of dienogest/ethinylestradiol should be restricted to second line and to women who also choose oral contraception.
- Since improvement of acne usually requires at least 3 months of treatment with dienogest/ethinylestradiol and further improvement has been seen after 6 months, women should be assessed 3 to 6 months after treatment initiation and periodically thereafter to review the need for continuation of treatment.

More about the medicine

Medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg are used as oral contraceptives and for the treatment of moderate acne. They have been authorised for up to 20 years 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 blocking the effects of a class of hormones called androgens. This alters the production of oils in the skin and also suppresses ovulation.

More about the procedure

The review of medicines containing dienogest 2 mg and ethinylestradiol 0.03 mg for acne was initiated on 25 February 2016 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 was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted the Agency's opinion. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States. Commission decision date: 22/03/2017.

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