



23 October 2014  
EMA/CHMP/654571/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

---

### Duavive

#### Conjugated Oestrogens / Bazedoxifene

On 23 October 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Duavive, 0.45 mg/20 mg modified-release tablets intended for the treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. The experience treating women older than 65 years is limited.

The applicant for this medicinal product is Pfizer Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Duavive are conjugated oestrogens and bazedoxifene.

The benefits with Duavive are following:

Conjugated estrogens substitute for the loss of oestrogen production in menopausal women, and alleviate menopausal symptoms. As oestrogens promote the growth of the endometrium, unopposed oestrogens increase the risk of endometrial hyperplasia and cancer. The addition of bazedoxifene, acting as an oestrogen receptor antagonist in the uterus, reduces the oestrogen-induced risk of endometrial hyperplasia.

The most common side effect is abdominal pain, occurring in more than 10% of patients in clinical trials.

A pharmacovigilance plan for Duavive will be implemented as part of the marketing authorisation.

The approved indication is: "the treatment of oestrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 months since the last menses) for whom treatment with progestin-containing therapy is not appropriate. The experience treating women older than 65 years is limited".

---

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Duavive and therefore recommends the granting of the marketing authorisation.