17 March 2011
EMA/CHMP/195947/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Zoely

nomegestrol acetate/estradiol

On 17 March 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zoely, 2.5/1.5 mg, film-coated tablet intended for oral contraception. The applicant for this medicinal product is Merck Serono Europe Ltd. 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 Zoely are nomegestrol acetate and estradiol, sex hormones and modulators of the genital system, progestogens and estrogens, fixed combinations (ATC code: G03A A14). Nomegestrol acetate is a highly selective progestogen derived from the naturally occurring steroid hormone, progesterone. The estrogen contained in Zoely is 17β-estradiol, a natural estrogen identical to the endogenous human 17β-estradiol. The contraceptive effect of Zoely is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the cervical secretion.

The benefit of Zoely is its ability to provide oral contraception. The most common side effects are acne, weight increased, headache and withdrawal bleeding irregular.

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

The approved indication is: "oral contraception. It is proposed that Zoely is prescribed by physicians experienced in the administration of oral contraceptives. 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 will be 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 Zoely and therefore recommends the granting of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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