European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 March 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ELLAONE

International Nonproprietary Name (INN): ***ulipristal acetate***

On 19 March 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product: Ellaone, 30 mg , tablets intended for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. The applicant for this medicinal product is Laboratoire HRA Pharma.

The active substance of Ellaone is ulipristal acetate, an synthetic selective progesterone receptor modulator with antagonistic and partial agonistic effects at the progesterone receptor *(ATC* Code not yet assigned). Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin and maintain pregnancy are not synthesized.

The benefits with Ellaone are its ability to prevent a pregnancy if used within 120 hours of unprotected intercourse. The most common side effects are Abdominal pain, menstrual disorders, nausea and headache.

A pharmacovigilance plan for Ellaone, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Ellaone, and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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