

FDA Approves Ella™ Tablets For Prescription Emergency Contraception

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[Washington, DC \(rushPRnews\)](#)

08/16/10 — The U.S. Food and Drug Administration approved ella™ (ulipristal acetate) tablets for emergency contraception. The prescription-only product prevents pregnancy when taken orally within 120 hours (five days) after a contraceptive failure or

unprotected intercourse. It is not intended for routine use as a contraceptive.

ella is a progesterone agonist/antagonist whose likely main effect is to inhibit or delay ovulation. Since May 2009, the prescription product has been available in Europe under the brand name ellaOne.

An FDA Advisory Committee for Reproductive Health Drugs discussed ella in June, 2010. The committee unanimously voted that the application for ella provided compelling data on efficacy and sufficient information on safety for the proposed indication of emergency contraception.

The safety and efficacy of ella were demonstrated in two Phase III clinical trials. One study was a prospective, multi-center, open-label, single-arm trial conducted in the United States; the other was a randomized, multi-center, single-blind

comparator-controlled trial conducted in the United States, United Kingdom and Ireland.

Side effects most frequently observed with ella in the clinical trials include: headache, nausea, abdominal pain, pain/discomfort during menstruation (dysmenorrhea), fatigue, and dizziness. The profile of side effects for ella is similar to that of FDA-approved levonorgestrel emergency contraceptives.

According to the product's labeling, women with known or suspected pregnancy and women who are breastfeeding should not use ella. A patient package insert also will be provided to ensure that women are fully informed of the benefits and risks involved in the use of ella.

ella is manufactured by Paris-based Laboratoire HRA Pharma. ella will be distributed by Watson Pharma Inc., of Morristown, N.J.

For more information:

[ella Labeling Information](#)

Editors note: Approved trade name is lower case 'e.'

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