EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ELLAONE

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Ellaone?
Ellaone is a medicine that contains the active substance ulipristal acetate. It is available as white tablets (30 mg).

What is Ellaone used for?
Ellaone is a female emergency contraceptive to be taken within five days of unprotected sex or contraceptive failure (such as a tear in a condom during sex). The medicine can only be obtained with a prescription.

How is Ellaone used?
Ellaone is taken as one tablet as soon as possible but no later than five days after unprotected sex or contraceptive failure. The tablet can be taken with or without food. If the woman vomits within three hours of taking the medicine she should take another tablet. Ellaone can be taken at anytime during the menstrual cycle.

How does Ellaone work?
For pregnancy to occur there has to be ovulation (release of eggs) followed by the fertilisation of the egg (fusion with a sperm) and implantation in the womb. The sex hormone progesterone stimulates the production of the proteins that play a role in the timing of ovulation and in preparing the lining of the womb to receive the fertilised egg.

The active substance in Ellaone, ulipristal acetate, acts as a progesterone receptor modulator. This means that it attaches to the receptors that progesterone normally attaches to, preventing the hormone from having its effect. Through its actions on the progesterone receptors, Ellaone prevents pregnancies by interfering with ovulation and it may also lead to changes in the lining of the womb.

How has Ellaone been studied?
The effects of Ellaone were first tested in experimental models before being studied in humans. In one main study, Ellaone was given to 1,533 women (aged on average 24 years) who had requested emergency contraception between two and five days after unprotected sex or contraceptive failure. The main measure of effectiveness was the number of women who did not become pregnant. This was then compared with the number of women who would have been expected to become pregnant if they had not taken any contraceptive, calculated from published rates.
The company also provided the results of an additional study comparing Ellaone with levonorgestrel (another medicine used in emergency contraception). This study included women who took the medicine within two days of unprotected sex or contraceptive failure.

**What benefit has Ellaone shown during the studies?**
Ellaone was effective as an emergency contraceptive. Of the women who completed the main study, 2.1% (26 out of 1,241) became pregnant. This is less than the 5.5% of women who would have been expected to become pregnant if they had not taken any contraceptive. Ellaone therefore prevented about three fifths of the expected pregnancies. The additional study, which included women who took the medicine within two days of unprotected sex or contraceptive failure, also supported the effectiveness of Ellaone.

**What is the risk associated with Ellaone?**
The most common side effects with Ellaone (seen in more than 1 patient in 10) are abdominal (tummy) pain and menstrual disorder (problems with periods). For the full list of all side effects reported with Ellaone, see the Package Leaflet.
Ellaone should not be used in women who may be hypersensitive (allergic) to ulipristal acetate or any of the other ingredients. It must not be used in women who are already pregnant.

**Why has Ellaone been approved?**
The Committee for Medicinal Products for Human Use (CHMP) decided that Ellaone’s benefits are greater than its risks for emergency contraception within five days of unprotected sexual intercourse or contraceptive failure. The Committee recommended that Ellaone be given marketing authorisation.

**Other information about Ellaone:**
The European Commission granted a marketing authorisation valid throughout the European Union for Ellaone to Laboratoire HRA Pharma on 15 May 2009.

The full EPAR for Ellaone can be found [here](#).

**This summary was last updated in 04-2009.**