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EPAR summary for the public

ellaOne

ulipristal acetate

This document is a summary of the European public assessment report (EPAR) for ellaOne. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for ellaOne.

What is ellaOne?

EllaOne is a medicine that contains the active substance ulipristal acetate. It is available as tablets (30 mg).

What is ellaOne used for?

EllaOne is a female emergency contraceptive to be taken within 120 hours (five days) of unprotected sex or contraceptive failure (such as a tear in a condom during sex).

The medicine can be obtained without a prescription.

How is ellaOne used?

EllaOne is taken as one tablet by mouth as soon as possible, but no later than 120 hours, after unprotected sex or contraceptive failure. If the woman vomits within three hours of taking the medicine she should take another tablet. EllaOne can be taken at any time during the menstrual cycle.

If a woman's menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before ellaOne is taken.

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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 plays a role in the timing of ovulation and in preparing the lining of 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 mainly by preventing or delaying ovulation. If ovulation has already occurred, ellaOne is no longer effective.

How has ellaOne been studied?

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 number was then compared with the number of women who would have been expected to become pregnant if they had not taken a contraceptive. This number was calculated from published pregnancy rates.

An additional study compared 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, reducing the number of unintended pregnancies. 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 pregnancies.

The additional study, which included women who took the medicine within two days of unprotected sex or contraceptive failure, supported the effectiveness of ellaOne. In this study, ellaOne was as effective as levonorgestrel at preventing pregnancies.

What is the risk associated with ellaOne?

The most common side effects with ellaOne are headache, nausea (feeling sick), abdominal pain (stomach ache) and dysmenorrhea (period pains). For the full list of all side effects and restrictions, see the package leaflet.

Why has ellaOne been approved?

The CHMP decided that ellaOne's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of ellaOne?

A risk management plan has been developed to ensure that ellaOne is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for ellaOne, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about ellaOne:

The European Commission granted a marketing authorisation valid throughout the European Union for ellaOne on 15 May 2009.

The full EPAR for ellaOne can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with ellaOne, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2014.