EPAR summary for the public

Esmya
ulipristal acetate

This is a summary of the European public assessment report (EPAR) for Esmya. 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 Esmya.

What is Esmya?

Esmya is a medicine that contains the active substance ulipristal acetate. It is available as tablets (5 mg).

What is Esmya used for?

Esmya is used before surgery to treat moderate to severe symptoms of uterine fibroids, which are noncancerous (benign) tumors of the womb (uterus). Esmya is used in adult women who have not yet reached menopause.

This medicine can only be obtained with a prescription.

How is Esmya used?

Esmya is taken by mouth and the recommended dose is one tablet daily. Treatment can last for up to three months and it should be started during the first week of the menstrual cycle (period bleeding).

How does Esmya work?

The active substance in Esmya, ulipristal acetate, is a ‘selective progesterone receptor modulator’. It acts by blocking the receptor of a hormone in the body called progesterone, which is involved in controlling the growth of the lining of the womb. In some women, progesterone may promote the growth of fibroids, which may cause symptoms such as heavy uterine bleeding (bleeding from the
womb during or outside the menstrual period), anaemia (low red blood cell counts, due to bleeding) and abdominal pain (such as period pain or pain in the belly area). When progesterone activity is blocked, fibroid cells stop dividing and eventually die, which reduces the size of the fibroids and reduces the symptoms caused by them.

**How has Esmya been studied?**

The effects of Esmya were first tested in experimental models before being studied in humans.

Two main studies involving 549 women with symptomatic uterine fibroids were carried out with Esmya. In both studies the treatment lasted for three months.

One study investigated the effects of Esmya compared with placebo (a dummy treatment) in adult women with heavy uterine bleeding and anaemia who were to undergo surgery to remove the fibroids. Iron supplements were also given to all the patients to help treat anaemia. The main measures of effectiveness were reductions in heavy bleeding and associated anaemia, as well as the size of the fibroids.

The second main study investigated the effects of Esmya in comparison with another medicine used to treat fibroids, leuprorelin. The main measure of effectiveness was the ability of the treatment to reduce heavy uterine bleeding.

**What benefit has Esmya shown during the studies?**

Esmya was shown to improve the symptoms of women with uterine fibroids.

In the first study, 91.5% of women taking Esmya had reduced menstrual bleeding compared with 18.8% of women taking placebo. The size of the fibroids was also smaller in women treated with Esmya than in those who received the placebo.

In the second study, Esmya was as effective as leuprorelin in reducing heavy uterine bleeding, as 90.3% of women treated with Esmya had reduced bleeding compared with 89.1% of women treated with leuprorelin.

**What is the risk associated with Esmya?**

The most common side effects with Esmya (seen in more than 1 in 10 patients) are amenorrhea (absence of menstrual period), endometrial thickening (thickening of the lining of the womb) and hot flush. For the full list of all side effects reported with Esmya, see the package leaflet.

Esmya must not be used in women who are hypersensitive (allergic) to ulipristal acetate or any of the other ingredients. It must not be used in women who are pregnant or breastfeeding, have bleeding from the genital region of unknown cause or for reasons other than uterine fibroids, or have cancer of the womb, cervix (the neck of the womb), ovary or breast. Treatment with Esmya should not be longer than three months. See the package leaflet for full details.

**Why has Esmya been approved?**

The CHMP concluded that Esmya was shown to be effective in reducing bleeding and anaemia as well as the size of the fibroids. There were no major safety concerns. Although endometrial thickening was seen in some patients, it normally disappears after treatment. Therefore, the CHMP concluded that the benefits of Esmya outweigh its risks and recommended that it be granted marketing authorisation. The Committee restricted treatment to three months due to the lack of longer-term data.
What measures are being taken to ensure the safe use of Esmya?

The company that markets Esmya will ensure that doctors who are expected to prescribe this medicine receive educational material containing important safety information about Esmya, including recommendations for monitoring and managing endometrial changes that occur with Esmya treatment.

Other information about Esmya

The European Commission granted a marketing authorisation valid throughout the European Union for Esmya on 23 February 2012.

The full EPAR for Esmya 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 Esmya, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2012.