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

It is used in women before they undergo surgery on their fibroids and can also be used long-term but with treatment breaks in other women.

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 a day for up to three months. The three-month treatment course can be repeated. Treatment should always be started during the first week of the menstrual cycle (period bleeding). For more information, see the package leaflet.

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?**

Esmya has been investigated in two main studies involving 549 women with symptomatic uterine fibroids who were to undergo surgery to remove the fibroids. In both studies the treatment lasted for three months (1 treatment course):

- The first study investigated the effects of Esmya compared with placebo (a dummy treatment) in adult women with heavy uterine bleeding and anaemia. 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.

Long-term treatment with Esmya has been investigated in a main study involving 451 women with symptomatic uterine fibroids who were given 4 three-month courses of Esmya. The main measure of effectiveness was the percentage of women who had no more than one day of spotting (minimal uterine bleeding) within a 35-day interval.

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

Esmya was shown to improve the symptoms of women with uterine fibroids who were to undergo surgery to remove the fibroids:

- In the first study, 91.5% of women taking Esmya for three months 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, three-month treatment with 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.

In the long-term study with Esmya, 49% of women receiving 5 mg Esmya (95 out of the 195 women who were assessed) had no more than one day of spotting within a 35-day interval after each of the 4 treatment courses, and 70% had no more than one day of spotting within a 35-day interval at the end of treatment course 4. A reduction in fibroid size was also observed.

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

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

**Why has Esmya been approved?**

The CHMP concluded that the benefits of Esmya outweigh its risks and recommended that it be granted marketing authorisation. The CHMP considered that Esmya was shown to be effective in reducing bleeding and anaemia as well as the size of the fibroids in women who were to undergo surgery for their fibroids. Esmya was also shown to be effective at reducing bleeding and fibroid size when used intermittently for longer periods (up to 4 treatment courses). There were no major safety concerns. Although endometrial thickening was seen in some patients, it normally disappeared after stopping treatment.

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

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

In addition, 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](http://ema.europa.eu/). For more information about treatment with Esmya, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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