Esmya (ulipristal acetate)
An overview of Esmya and why it is authorised in the EU

What is Esmya and what is it used for?

Esmya is a medicine used to treat moderate to severe symptoms of uterine fibroids in adult women who have not yet reached the menopause. Uterine fibroids are non-cancerous (benign) tumours of the womb (uterus).

Esmya can be given:

- as a single treatment course in women before they have surgery for their fibroids;
- as intermittent treatment for women in whom surgery is not suitable.

The medicine contains the active substance ulipristal acetate.

How is Esmya used?

Esmya can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of uterine fibroids.

It is available as tablets (5 mg) to be taken by mouth. The recommended dose is one tablet a day for up to three months (one treatment course). The three-month treatment course can be repeated in women in whom surgery is not suitable. Treatment should always be started during the first week of the menstrual period.

For more information about using Esmya, see the package leaflet or contact your doctor or pharmacist.

How does Esmya work?

The active substance in Esmya, ulipristal acetate, blocks the activity of progesterone, a hormone in the body involved in controlling the growth of the lining of the womb. In some women, progesterone may promote the growth of fibroids, which can 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). When progesterone activity is blocked, fibroid cells stop dividing and eventually die, which reduces the size of the fibroids and the symptoms caused by them.
What benefits of Esmya have been shown in studies?

Esmya improved the symptoms of uterine fibroids in two main studies involving 549 women who were to have surgery to remove the fibroids.

In the first study, uterine bleeding was reduced in 92% of women taking Esmya for three months (one treatment course) compared with 19% of women taking placebo (a dummy treatment). The size of the fibroids was also smaller in women treated with Esmya than in those who received placebo.

In the second study, Esmya taken for three months was as effective as leuprorelin (another medicine for fibroids) in reducing heavy uterine bleeding, with bleeding reduced in 90% of women treated with Esmya compared with 89% of women treated with leuprorelin.

Long-term treatment with Esmya has been investigated in a main study involving 451 women who were given 4 three-month courses of 5 or 10 mg of 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 (minimal uterine bleeding) within a 35-day interval after each treatment course, and 70% had no more than one day of spotting within a 35-day interval at the end of the fourth treatment course. A reduction in fibroid size was also observed.

What are the risks associated with Esmya?

The most common side effects with Esmya (which may affect 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, have cancer of the womb, cervix (the neck of the womb), ovary or breast, or have liver problems. For the full list of restrictions, see the package leaflet.

Why is Esmya authorised?

The European Medicines Agency decided that the benefits of Esmya outweigh its risks and it can be authorised for use in the EU. Esmya has been shown to be effective in reducing symptoms as well as the size of the fibroids in women who were to have surgery for their fibroids and when used intermittently for longer periods (up to 4 treatment courses). Rare but serious cases of liver injury have been reported with the medicine and measures have been put in place to minimise this risk.1 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?

The company that markets Esmya will ensure that doctors who are expected to prescribe this medicine receive educational material with information about the safety of Esmya, including recommendations for monitoring liver function and endometrial changes during treatment. A card will also be given to patients to inform them about the need for liver monitoring and to contact their doctor if they develop symptoms of liver injury (such as tiredness, yellowing of the skin, darkening of the urine, nausea and vomiting).

---

1 See outcome of safety review carried out in 2018 here.
Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Esmya have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Esmya are continuously monitored. Side effects reported with Esmya are carefully evaluated and any necessary action taken to protect patients.

**Other information about Esmya**

Esmya received a marketing authorisation valid throughout the European Union on 23 February 2012.

Further information on Esmya can be found on the Agency’s website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](https://ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports).

This overview was last updated in 07-2018.