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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 for treating moderate to severe symptoms of uterine fibroids. Uterine fibroids are non-cancerous (benign) tumours of the womb (uterus).

Esmya is for use only in women who have not yet reached the menopause and in whom fibroid embolisation (a non-surgical procedure to block off the arteries that feed the fibroids) or surgery are not suitable or have not worked.

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.

Esmya is available as tablets (5 mg) to be taken by mouth. The recommended dose is one tablet a day for up to 3 months (one treatment course). The treatment course can be repeated. Treatment should always start 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 involved in controlling growth of the womb lining. In some women, progesterone may promote the growth of fibroids, which can cause heavy uterine bleeding (bleeding from the womb during or outside the menstrual period), anaemia (low red blood cell counts) and abdominal pain (such as period pain). When progesterone activity is blocked, fibroid cells stop dividing and eventually die, which shrinks the fibroids and reduces the symptoms they cause.

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.

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In the first study, uterine bleeding was reduced in 92% of women taking Esmya for 3 months (one treatment course) compared with 19% of women taking placebo (a dummy treatment). The size of the fibroids was also smaller after treatment with Esmya than with placebo.

In the second study, Esmya taken for 3 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 four 3-month courses of Esmya. In women taking Esmya 5 mg, 49% (95 out of the 195 women who were assessed) had no more than one day of spotting (minimal uterine bleeding) within 5 weeks after each treatment course, and 70% had no more than one day of spotting within 5 weeks at the end of the fourth treatment course. Fibroid size was also reduced.

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), endometrial thickening (thickening of the lining of the womb) and hot flushes.

Esmya must not be used in women who are pregnant or breastfeeding, have bleeding from the genital region 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 side effects and restrictions of Esmya, see the package leaflet.

Why is Esmya authorised?

Esmya is effective in reducing symptoms as well as the size of uterine fibroids when used for up to 4 treatment courses.

Because rare but serious cases of liver injury (with a need for liver transplantation) have occurred in women taking the medicine, the European Medicines Agency has recommended that it should be restricted for use only in women in whom surgery or uterine fibroid embolisation are not suitable or they have not worked. Measures have been introduced to minimise the risk of severe liver injury.[1] Although endometrial thickening occurred in some patients, it generally disappeared after stopping treatment.

The Agency therefore decided that the benefits of Esmya outweigh its risks and it can be authorised for use in the EU.

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 its safety, including recommendations for discussion of all the treatment options with patients, and monitoring liver function and endometrial changes during treatment. A card will also be given to patients about the risk of liver injury, 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 2020 here.

Recommendations and precautions 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/medicines/human/EPAR/esmya

This overview was last updated in 12-2020.