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Ulipristal Acetate Gedeon Richter (*ulipristal acetate*)

An overview of Ulipristal Acetate Gedeon Richter and why it is authorised in the EU

What is Ulipristal Acetate Gedeon Richter and what is it used for?

Ulipristal Acetate Gedeon Richter is a medicine for treating moderate to severe symptoms of uterine fibroids. Uterine fibroids are non-cancerous (benign) tumours of the womb (uterus).

Ulipristal Acetate Gedeon Richter 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.

Ulipristal Acetate Gedeon Richter contains the active substance ulipristal acetate.

This medicine is the same as Esmya, which is already authorised in the EU. The company that makes Esmya has agreed that its scientific data can be used for Ulipristal Acetate Gedeon Richter ('informed consent').

How is Ulipristal Acetate Gedeon Richter used?

Ulipristal Acetate Gedeon Richter 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.

Ulipristal Acetate Gedeon Richter 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 Ulipristal Acetate Gedeon Richter, see the package leaflet or contact your doctor or pharmacist.

How does Ulipristal Acetate Gedeon Richter work?

The active substance in Ulipristal Acetate Gedeon Richter, 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

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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 Ulipristal Acetate Gedeon Richter have been shown in studies?

Ulipristal Acetate Gedeon Richter 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 the medicine 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 Ulipristal Acetate Gedeon Richter than with placebo.

In the second study, Ulipristal Acetate Gedeon Richter 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 Ulipristal Acetate Gedeon Richter compared with 89% of women treated with leuprorelin.

Long-term treatment with the medicine has been investigated in a main study involving 451 women who were given four 3-month courses of Ulipristal Acetate Gedeon Richter. In women taking Ulipristal Acetate Gedeon Richter 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 Ulipristal Acetate Gedeon Richter?

The most common side effects with Ulipristal Acetate Gedeon Richter (which may affect more than 1 in 10 patients) are amenorrhoea (absence of menstrual period), endometrial thickening (thickening of the lining of the womb) and hot flushes.

Ulipristal Acetate Gedeon Richter 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 Ulipristal Acetate Gedeon Richter, see the package leaflet.

Why is Ulipristal Acetate Gedeon Richter authorised in the EU?

Ulipristal Acetate Gedeon Richter 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 was seen in some patients, it generally disappeared after stopping treatment.

[1] See outcome of safety review carried out in 2020 here.

The Agency therefore decided that the benefits of Ulipristal Acetate Gedeon Richter 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 Ulipristal Acetate Gedeon Richter?

The company that markets Ulipristal Acetate Gedeon Richter 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).

Recommendations and precautions for the safe and effective use of Ulipristal Acetate Gedeon Richter have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Ulipristal Acetate Gedeon Richter

Ulipristal Acetate Gedeon Richter received a marketing authorisation valid throughout the EU on 27 August 2018.

Further information on Ulipristal Acetate Gedeon Richter can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ulipristal-acetate-gedeon-richter.

This overview was last updated in 12-2020.