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EMA starts review of Esmya for uterine fibroids

Review triggered by cases of liver injury

The European Medicines Agency (EMA) has started a review of the medicine Esmya (ulipristal acetate) used to treat uterine fibroids (non-cancerous tumours of the womb). This follows four reports of serious liver injury, three of which ended in liver transplantation, in patients treated with the medicine.[1]

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has made an initial assessment of the cases of liver injury and considered that Esmya could be the cause.

Given the seriousness of the observed liver injury and its possible link to the medicine, a more in depth review is warranted.

The PRAC will now evaluate all available data and determine whether there are any implications for the use of Esmya.

While the review is ongoing, patients should contact their doctor if they have any questions or concerns about their treatment.

Ulipristal acetate is also the active substance of a single-dose medicine authorised for emergency contraception, ellaOne. No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.

More about the medicine

Esmya was first authorised in the EU in 2012 for the treatment of moderate to severe symptoms of uterine fibroids, which are non-cancerous (benign) tumours of the womb, in women who have not reached the menopause. It is used for up to 3 months before women undergo surgery to remove the fibroids. The 3-month course can be repeated with breaks between each course.

The active substance in Esmya, ulipristal acetate, works by attaching to the targets on cells (receptors) that the hormone progesterone normally attaches to, preventing progesterone from having its effect.

[1] It is estimated that around 670,000 patients have been treated with Esmya to date.

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Since progesterone may promote the growth of fibroids, by preventing the effects of progesterone ulipristal acetate reduces the size of the fibroids.

More information on Esmya can be found here.

More about the procedure

The review of Esmya has been initiated at the request of European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.