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PRAC recommends revoking marketing authorisation of ulipristal acetate for uterine fibroids

A review by EMA's safety committee (PRAC) has confirmed that 5-mg ulipristal acetate (Esmya and generic medicines) used for the treatment of symptoms of uterine fibroids can cause liver injury, including the need for liver transplantation. The PRAC has therefore recommended the revocation of the marketing authorisations of these medicines.

The PRAC considered all the available evidence in its review, including reported cases of serious liver injury. Patient and healthcare professional representatives, including experts in gynaecology, were also consulted. Since it was not possible to identify which patients were most at risk or measures that could reduce the risk, the PRAC concluded that the risks of these medicines outweighed their benefits and that they should not be marketed in the EU.

The use of 5-mg ulipristal acetate medicines for uterine fibroids had already been suspended as a precautionary measure while awaiting the outcome of this review.

Ulipristal acetate is also authorised as a single-dose medicine for emergency contraception. This recommendation does not affect the single-dose ulipristal acetate emergency contraceptive (ellaOne and other trade names) and there is no concern about liver injury with these medicines.

The PRAC recommendation will now be forwarded to EMA's human medicines committee (CHMP), which will adopt the Agency's opinion.

More about the medicines

Ulipristal acetate was authorised for treating moderate to severe symptoms of uterine fibroids, which are non-cancerous tumours of the womb, in women who have not reached the menopause. It was used for up to 3 months before women had surgery to remove the fibroids and was also used long-term but with treatment breaks in other women.

Esmya (ulipristal acetate) was authorised throughout the EU in 2012. Esmya was the subject of a previous review in 2018. Ulipristal Acetate Gedeon Richter was authorised throughout the EU in 2018.

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Generic ulipristal acetate medicines have been authorised via national procedures in several EU countries under various trade names.

More information on Esmya and Ulipristal Acetate Gedeon Richter is available on the EMA website.

More about the procedure

The review of Esmya, Ulipristal Acetate Gedeon Richter and generics was initiated at the request of the European Commission, under Article 31 of Directive 2001/83/EC.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines.

On 12 March 2020, the PRAC recommended suspension of the marketing authorisations of 5-mg ulipristal acetate (Esmya and generic medicines) while the review was ongoing. The European Commission issued a legally binding decision to suspend the marketing authorisation on 25 March 2020.

The PRAC recommendations will now 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.