



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2020
EMA/160220/2020

Suspension of ulipristal acetate for uterine fibroids during ongoing EMA review of liver injury risk

On 12 March 2020, EMA's safety committee (PRAC) recommended women to stop taking 5-mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids while a safety review is ongoing. No new patients should start treatment with the medicines, which will be temporarily suspended throughout the EU during the review.

EMA is starting its review at the request of the European Commission following a recent case of liver injury, which led to liver transplantation in a patient taking the medicine.

A [2018 EMA review](#) concluded that there is a risk of rare but serious liver injury with ulipristal acetate medicines for the treatment of uterine fibroids, and measures were implemented to minimise the risk. However, as the new case of serious liver injury occurred in spite of adherence to these measures, EMA is starting a new review.

Cases of serious liver injury have been reported, including 5 that led to transplantation, out of over 900,000 patients who have been treated with ulipristal acetate for fibroids since its authorisation in 2012.

Ulipristal acetate is also authorised as a single-dose medicine for emergency contraception. This review 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.

Further information and updated recommendations will be provided once the review is concluded.

Information for patients

- Patients should stop taking ulipristal acetate for uterine fibroids (non-cancerous tumours of the womb) while EMA's safety committee reviews data on the safety of these medicines. The review has started following a case of serious liver injury resulting in liver transplantation that has occurred in a woman taking ulipristal acetate for uterine fibroids.
- If you are taking ulipristal acetate for uterine fibroids, contact your doctor for advice on other possible treatments.
- Consult your doctor or pharmacist if you have any questions or concerns about your treatment.
- Contact your doctor immediately if you develop symptoms of liver injury such as tiredness, loss of appetite, abdominal pain, yellowing of the skin, darkening of the urine, nausea and vomiting.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



- There is no concern about liver injury with the single-dose emergency contraceptive containing ulipristal acetate (ellaOne and other trade names).

Information for healthcare professionals

- Contact your patients currently being treated with ulipristal acetate for uterine fibroids as soon as possible and stop their treatment. Consider other treatment options as appropriate.
- Advise patients to immediately report signs and symptoms of liver injury (such as nausea, vomiting, right hypochondrial pain, anorexia, asthenia and jaundice).
- Liver function testing should be performed 2–4 weeks after treatment has stopped as described in the product information for the medicines.
- Do not start any new patients on ulipristal acetate for uterine fibroids.

A direct healthcare professional communication (DHPC) has been sent on or soon after 23 March 2020 to healthcare professionals prescribing or dispensing the medicines. The DHPC will also be published on a [dedicated page](#) on the EMA website.

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 and Ulipristal Acetate Gedeon Richter in 2018. 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 has been initiated at the request of the European Commission, under [Article 31 of Directive 2001/83/EC](#).

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. While the review is ongoing, the PRAC has recommended suspending the medicines as an interim measure to protect public health. The recommendation has been forwarded to the European Commission (EC), which issued a provisional legally binding decision applicable in all EU Member States on 25 March 2020.

Once the PRAC review is concluded, the final 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.