

19th February 2018

Direct Healthcare Professional Communication

Restrictions on the use of ulipristal acetate, Esmya 5 mg tablet, and important new warnings of serious liver injury and recommendations for liver monitoring

Dear Healthcare Professional,

Gedeon Richter Plc. in agreement with the European Medicines Agency (EMA), and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

EMA is reviewing the benefits and risks with ulipristal acetate (Esmya). The review was initiated following reports of serious liver injury, including acute liver failure leading to transplantation, in patients treated with Esmya. The following temporary measures have been agreed until the review is finalized, to better protect patients:

Summary

- **Esmya treatment should not be initiated in new patients or in patients who have finalised a previous treatment course.**
- **For patients on treatment with Esmya, liver function should be monitored at least monthly, and 2-4 weeks after stopping treatment.**
- **If a patient shows signs or symptoms compatible with liver injury (nausea, vomiting, right hypochondrial pain, anorexia, asthenia, jaundice, etc.), the patient should be investigated immediately and liver function tests performed. Patients who develop transaminase levels > 2 times the upper limit of normal during Esmya treatment should stop treatment and be closely monitored.**
- **Patients should be advised about specific actions to take in the event of signs and symptoms of liver injury as described above.**

Background on the safety concern

Esmya is indicated for pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Following reports of serious liver injury, a review of the benefits and risks of Esmya was initiated by EMA. Until a thorough assessment of the available data is performed within the ongoing review, temporary measures are considered needed to minimise potential risks to patients.

Call for reporting

Healthcare professionals should report any adverse reactions associated with the use of Esmya in accordance with the national spontaneous reporting system via the MHRA Yellow Card Scheme; Website: www.mhra.gov.uk/yellowcard

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Your sincerely,



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