New important information on safety of medicine Esmya, 5 mg tablets

19 March 2020

Ulipristal acetate 5 mg for uterine fibroids not to be used during ongoing review of liver injury risk

Dear Healthcare Professional,

«Gedeon Richter» Plc. (Hungary) in agreement with the «Scientific Centre of Drug and Medical Technology Expertise After Academician E.Gabrielyan» would like to inform you of the following:

EMA is reviewing the benefits and risks with ulipristal acetate 5 mg for the treatment of uterine fibroids. The review was initiated following one new case report of serious liver injury leading to transplantation in a patient treated with Esmya 5 mg (ulipristal acetate). The following temporary measures have been agreed until the review is finalised.

Summary

- Ulipristal acetate 5 mg is temporarily withdrawn from the market during the ongoing review.
- For patients on treatment with ulipristal acetate 5 mg the treatment must be stopped.
- Ulipristal acetate 5 mg should not be initiated in patients.
- Liver monitoring should be performed within 2-4 weeks after treatment has stopped.
- Patients should be advised to immediately report signs and symptoms of liver injury (such as nausea, vomiting, right hypochondrial pain, anorexia, asthenia, jaundice), which could occur after stopping treatment.

Background on the safety concern

Ulipristal acetate 5 mg is currently approved in the EU for the following indications:

- ulipristal acetate is indicated for one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age

- ulipristal acetate is indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery.

In 2018, the Pharmacovigilance Risk Assessment Committee (PRAC) finalized a review of Esmya 5 mg (ulipristal acetate) initiated due to reports of serious liver injury, including four cases requiring liver transplantation. To minimize the risk, the use of ulipristal acetate 5 mg was restricted and recommendations for regular liver function tests were issued. In December 2019, EMA was informed of a new case of serious liver injury leading to liver transplantation following treatment with Esmya (ulipristal acetate).

In view of the seriousness of this case and its occurrence despite adherence to the risk minimisation measures implemented in 2018, ulipristal acetate 5 mg-containing products must not be used while a review of the benefits and risks of these products is ongoing at EU level.

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 of liver injury with these medicines.

Call for reporting

We ask the healthcare professionals to report any adverse reactions associated with the use of ulipristal acetate 5 mg in accordance with the national spontaneous reporting system approved in Armenia.

All suspected adverse reactions connected with the use of ulipristal acetate 5 mg tablets should be reported to the «Scientific Centre of Drug And Medical Technology Expertise After Academician E. Gabrielyan» according to the approved mode:

- On-line – filling the report form on the site www.pharm.am,
- On paper – downloading, printing and filling the report form,
- By hot line – phone numbers +374 10 20 50 50, 096 22 50 50,
- By Med Safety mobile application.

All suspected adverse reactions caused by the medicines of «Gedeon Richter» can be sent to the marketing authorization holder e-mail address drugsafety@gedeonrichter.am
or to the address: «Gedeon Richter» Plc. (Hungary) Representation in Armenia, 0010, Yerevan, Zakyan 2
or on the phone numbers +37410530071, +37491203347