



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 18 March 2020

EL (20)A/16

Our Ref: MDR 077-03/20

Dear Healthcare Professional,

Gedeon Richter (UK) Ltd

Esmya 5 mg tablets

EU/1/12/750/001
EU/1/12/750/002
EU/1/12/750/003
EU/1/12/750/004
EU/1/12/750/005

Generic Name: ulipristal acetate

Gedeon Richter (UK) Ltd is recalling all unexpired stock of the above products from patients, pharmacies and wholesalers following a new case of liver failure requiring liver transplant in a patient taking the medicine. To protect patients while a safety review is conducted, the European Medicines Agency's safety committee, Pharmacovigilance Risk Assessment Committee, (PRAC) has recommended that women stop taking 5mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids.

Note: This recall does not affect the 30mg single dose ulipristal acetate emergency contraceptive products.

Advice for healthcare professionals

- Contact patients who have been supplied Esmya and ask them to stop taking their medication as soon as possible and return any unused medicine to their pharmacy. All patients currently being treated with Esmya/ulipristal acetate for uterine fibroids should contact their doctor for advice about other possible treatments for uterine fibroids.
- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Stop prescribing Esmya or generic ulipristal acetate for the treatment of uterine fibroids. No new patients should start treatment with the medicines, which has been suspended throughout the EU during the review. Consider other treatment options as appropriate.
- Liver function testing should be performed 2- 4 weeks after treatment has stopped as described in the product information for the medicines.
- Healthcare professionals should alert patients 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.



Company contacts for further information

For stock control and/or medical information enquiries please contact Gedeon Richter (UK) Ltd on +44 (0) 1279 406 759

Recipients should bring it to the attention of relevant contacts by copy of this letter.

NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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