15 February 2019

IMPORTANT SAFETY UPDATE:
ESMYA® (ulipristal acetate 5mg)

Dear Healthcare Professional,

Vifor Pharma in agreement with the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), would like to inform you of important safety information regarding Esmya® (ulipristal acetate 5mg) and serious liver injury.

Background
Following reports of serious liver injury, including acute liver failure leading to transplantation, a review of the benefits and risks of Esmya® was undertaken by the European Regulator (the European Medicines Agency), with a concurrent review undertaken by Medsafe's Medicines Adverse Reactions Committee (MARC). The resulting investigation necessitated a restriction to the indication, addition of contraindication, and requirement for hepatic monitoring which are now reflected in the current Data Sheet for Esmya®.

Restriction to indication and addition of contraindication
Esmya® is now indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery.

Esmya® is now contraindicated in patients with an underlying hepatic disorder.

Additional Monitoring Requirements
The following requirements have been added to the Data Sheet under *Special warnings and precautions for use, Hepatic injury*:

- Liver function tests must be performed before starting treatment. Treatment must not be initiated if transaminases (alanine transaminase (ALT) or aspartate aminotransferase (AST)) are above the upper limit of normal.
- During treatment, liver function tests must be performed after one week and then once a month during the first two treatment courses.
- For further treatment courses, liver function must be tested once before each new treatment course and when clinically indicated.
- If a patient during treatment shows signs or symptoms compatible with liver injury (fatigue, asthenia, nausea, vomiting, right hypochondrial pain, anorexia, jaundice), treatment should be stopped and the patient should be investigated immediately, and liver function tests performed.

In order to assist physicians and patients with these monitoring requirements, a Patient Card will be included on the rear of each Consumer Medicine Information (CMI), a copy of which is included in each pack of Esmya®. The Patient Card serves to inform patients of the need for liver monitoring, assist patients and physicians in scheduling and tracking required liver function tests, and advises patients to contact their physician should they develop signs of liver injury.

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with this product to CARM (https://nzphvc.otago.ac.nz/reporting/) or to the Vifor Pharma pharmacovigilance team on 0800 996 312 or Medinfo_AUS@viforpharma.com

Prescribers are advised to review the full Data Sheet before prescribing Esmya®. If you have any further questions relating to Esmya® please contact Vifor Pharma Medical Information on 0800 996 312.

CONTACT

MEDICAL INFORMATION

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Yours sincerely,

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