alfred gera &sons LTD
Trading Since 1888
"Over 100 Years of Trading"

Triq il-Masġar, Qormi, QRM 3217, Malta.
Telephone: (+356) 2144 6205 Facsimile: (+356) 2144 5111
E-mail: main@alfredgera.com Company Reg. No. C120

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 Malta Medicines Authority 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.**

alfred gera &sons LTD
Trading Since 1888
"Over 100 Years of Trading"

Triq il-Masġar, Qormi, QRM 3217, Malta.
Telephone: (+356) 2144 6205 Facsimile: (+356) 2144 5111
E-mail: main@alfredgera.com Company Reg. No. C120

- **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

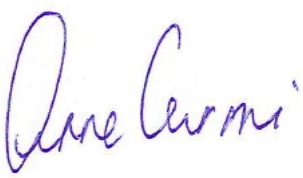
Esmya is indicated for pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Following reports of serious liver injury, a review of the benefits and risks of Esmya was initiated by EMA. Until a thorough assessment of the available 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 ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

Yours sincerely

On behalf of Gedeon Richter



Anne Curmi

Pharmacoviligance Head

Alfred Gera and Sons Ltd