# EMA recommends monthly liver function tests for women treated with Esmya

10.05.18 | Circular Number P04/2018

## Information on Esmya

- Esmya (ulipristal acetate) is a medicinal product to treat moderate to severe symptoms of uterine fibroids. It is used for up to 3 months before women undergo surgery to remove the fibroids and can also be used long-term with treatment breaks in other women.
- Ulipristal acetate works by attaching to the targets on cells (receptors) that the hormone progesterone normally attaches to, preventing progesterone from having its effect. Since progesterone may promote the growth of fibroids, by preventing the effects of progesterone ulipristal acetate reduces the size of the fibroids.

In Malta, Esmya is authorised through the centralised procedure

## Information on EMA ongoing review of Esmya and the PRAC's temporary recommendations

The review of Esmya was initiated at the request of European Commission on 30 November 2017, under Article 20 of Regulation (EC) No 726/2004. The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) is currently carrying out the review and has recommended regular liver monitoring for women taking Esmya for uterine fibroids. The PRAC is currently reviewing the risk benefit balance of Esmya.

The PRAC's **temporary** recommendations are:

- Women taking Esmya should have a liver function test at least once a month during treatment
- If the test is abnormal (liver enzyme levels more than 2 times the upper limit of normal), the healthcare professional should stop treatment
- Liver tests should be repeated 2 to 4 weeks after stopping treatment
- No new patients should be started on Esmya. No patients who have completed a course of treatment should start another one for the time being.

The PRAC's final recommendations will be forwarded to the Committee for Medicinal Products for Human Use (CHMP which will adopt an opinion. The European Commission will issue a legally binding decision applicable in all EU Member States in due course.

**In Malta**

**For Healthcare Professionals**

Following reports of liver injury and hepatic failure with Esmya, EMA has made the following **temporary** recommendations:

- Do not start new patients on Esmya or new treatment courses in patients who have already completed a previous one
- Perform liver function tests at least once a month for all patients taking Esmya. If the patient develops transaminase levels more than 2 times the upper limit of normal, stop treatment and monitor the patient closely. Liver test should be repeated 2 to 4 weeks after stopping treatment.
- For any patient with signs or symptoms consistent with liver injury (such as nausea, vomiting, right hypochondrial pain, anorexia, asthenia, jaundice), check transaminase levels immediately. If transaminase levels are more than 2 times the upper limit of normal, stop treatment and closely monitor the patient.
- Advise your patients about the signs and symptoms of liver injury

A DHPC letter about the safety concern has been disseminated to HCPs in Malta. Archived DHPC letters are available online at http://www.medicinesauthority.gov.mt/dhpc

**Advice for Patients**

- Esmya, used to treat uterine fibroids, is being reviewed because cases of serious liver problems have occurred in women taking the medicine
- If you have nausea (feeling sick), vomiting, upper belly pain, lack of appetite, tiredness or yellowing of the eyes or skin, contact your doctor immediately as these could be signs of liver problems
- If you were about to start treatment with Esmya or start a new course of treatment, your doctor will put your treatment on hold until EMA's review of the medicine is complete
- If your treatment is stopped, your doctor will check how well your liver is working 2 to 4 weeks after you stop taking Esmya.

For more information on the Esmya review visit the European Medicines Agency's Esmya referral webpage

**Reporting Adverse Drug Reactions**

Healthcare professionals and patients are encouraged to maintain vigilance on Gadolinium contrast agents. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: **http://www.medicinesauthority.gov.mt/adrportal**) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to **postlicensing.medicinesauthority@gov.mt** or to the marketing authorisation holder or their local representatives.

**Post-Licensing Directorate**
**Medicines Authority**

***Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.***

**Feedback Form**

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

**Feedback:**

We thank you for your interest and look forward to hearing your opinion.

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