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Direct Healthcare Professional Communication

10th December 2020

Ulipristal acetate 5 mg: Indications for uterine fibroids restricted due to concerns of severe liver injury

Dear Healthcare Professional,

Gedeon Richter Plc. in agreement with the European Medicines Agency (EMA), and the Malta Medicines Authority would like to inform you about new restrictions on the use of ulipristal acetate 5 mg and additional measures to minimise the risk of serious liver injury:

Summary

- **Cases of serious liver injury (including those necessitating liver transplantation) have followed the use of ulipristal acetate 5 mg for treating moderate to severe symptoms of uterine fibroids.**
- **The use of ulipristal acetate 5 mg must now be considered only for intermittent treatment of moderate to severe symptoms of uterine fibroids in women who have not reached menopause and when uterine fibroid embolisation or surgery are not suitable or have failed.**
- **The physician must discuss with patients the risks and benefits of available alternatives so patients can make an informed decision.**
- **The risks of ulipristal acetate 5 mg should be fully explained to patients, especially the risk of liver injury, which could in rare cases lead to liver transplantation.**
- **Patients should be informed about possible signs and symptoms of liver injury, and if patients get such symptoms, they must stop treatment and contact their doctor immediately.**

Background on the safety concern

In 2018, a review of ulipristal acetate 5 mg was carried in the light of reports of four cases of serious liver injury leading to liver transplantation. As a result, several measures were recommended to minimise the risk of serious liver injury, including restriction in indication, a contraindication, and liver function monitoring.

Recently, a new (fifth) case of serious liver injury leading to liver transplantation has been reported. Having ruled out other plausible aetiologies, ulipristal acetate was considered to be the most likely cause of acute hepatitis leading to acute liver failure and liver transplantation.

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A second European review concluded that in addition to the previous measures, the indication of ulipristal acetate 5 mg should be further restricted. The risk of severe liver injury does not justify its use for pre-operative treatment of uterine fibroids.

Besides, it is vital to properly and sufficiently communicate the benefits and risks of ulipristal acetate 5 mg to patients – in particular, the risk of liver injury and its possible signs and symptoms, which could in rare cases lead to liver transplantation. If patients experience such symptoms, they should stop treatment, and contact their doctor immediately. Patients should also be informed of the need for liver monitoring before, during and after treatment courses. For this reason, patients should carefully read the patient alert card included in the medicine's package.

These measures will be introduced in the summary of product characteristics (SmPC) of ulipristal acetate 5 mg. The Physician's guide and the Patient alert card will also be updated.

Call for reporting

Healthcare professionals should report any adverse reactions associated with the use of ulipristal acetate 5 mg in accordance with the national spontaneous reporting system on Website: *www.medicinesauthority.gov.mt/adrportal*.

Company contact point

For any further information kindly send an email to pv@alfredgera.com or telephone 21446205.

Yours sincerely

Anne Curmi

Pharmacovigilance Country Head