April 3, 2020

Re: Important Update on FIBRISTAL® (ulipristal acetate) 5 mg tablet

Dear customer,

We would like to share an important update on ESMYA® (ulipristal acetate) 5 mg tablets in Europe.

The European Medicines Agency (EMA) has requested a safety review of ESMYA® (brand name FIBRISTAL® in Canada) following a recent case of liver injury which led to liver transplantation in a patient.

The EMA's safety committee, the Pharmaceutical Risk Assessment Committee (PRAC) has recommended the following:

"Women to stop taking 5-mg ulipristal acetate for uterine fibroids while a safety review is ongoing. No new patients should start treatment with the medicines, which will be temporarily suspended throughout the European Union (EU) during the review."

Upon learning of the PRAC decision, Allergan notified Health Canada on March 13, 2020 of the notice of suspension of ESMYA® in the EU while PRAC is conducting a review of the risk/benefit profile of ulipristal acetate. Allergan has also notified Canadian physicians of this new information. A final recommendation from PRAC is expected by **September 30, 2020**.

Since its authorization in 2012, an estimated 900,000 patients have been treated for fibroids with ulipristal acetate. In that time there have been reports of cases of serious liver injury, including 5 that led to transplantation. Four of these cases were included in a 2018 risk assessment and one additional case has recently occurred. The notable issue is that this recent case was reported despite the risk minimization measures implemented (i.e. the liver function monitoring).

No Canadian cases of liver transplant have been reported to date, although cases of liver injury, some severe, have been reported. During this time, FIBRISTAL® continues to be available in Canada.

Ulipristal acetate is also approved as a single-dose medicine for emergency contraception (ella®). The EMA's review does not affect this use and there is no concern of liver injury with this medication.

We recognize the potential seriousness and importance of this situation. Patient safety is of upmost importance to Allergan. We have been and will continue to work with regulators to ensure the safe use of this medication.

For more information on the PRAC assessment, please go to:
https://www.ema.europa.eu/en/medicines/human/referrals/ulipristal-acetate-5mg-medicinal-products

Sincerely,

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