

## Prescribing of ulipristal acetate (Esmya) 5mg tablets

**Thurrock, and Basildon and Brentwood CCG do not support the prescribing of ulipristal acetate (Esmya).**

Ulipristal acetate (Esmya) 5mg tablets are used to treat moderate to severe uterine fibroids in adult women who have not yet reached the menopause. It is normally taken for up to three months but the course can be repeated.

As of 18<sup>th</sup> March 2020 the manufacturer Gedeon Richter (UK) has recalled this medicine from patients, pharmacies and wholesalers following a new case of liver failure requiring liver transplant in a patient taking the Medicine. To protect patients while a safety review is conducted, the European Medicines Agency's safety committee, Pharmacovigilance Risk Assessment Committee, (PRAC) has recommended that women stop taking 5mg ulipristal acetate (Esmya and generic medicines) for uterine fibroids. ***This recall does not affect the 30mg single dose ulipristal acetate emergency contraceptive products.***

### Advice for healthcare professionals:

- Contact patients who have been supplied Esmya and ask them to stop taking their medication as soon as possible and return any unused medicine to their pharmacy. All patients currently being treated with Ulipristal acetate (Esmya) for uterine fibroids should contact their doctor for advice about other possible treatments for uterine fibroids.
- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Stop prescribing Esmya or generic ulipristal acetate for the treatment of uterine fibroids. No new patients should start treatment with the medicines, which has been suspended throughout the EU during the review. Consider other treatment options as appropriate.
- Liver function testing should be performed 2- 4 weeks after treatment has stopped as described in the product information for the medicines.
- Healthcare professionals should alert patients to immediately report signs and symptoms of liver injury (such as nausea, vomiting, right hypochondrial pain, anorexia, asthenia, jaundice) which could occur after stopping treatment.

Providers commissioned to provide services on behalf of Thurrock CCG and Basildon and Brentwood CCG are reminded that they are required to follow the local joint formulary and prescribing guidance, or relevant Medicines Management agreement.

<b>Position Statement No.</b>	39
<b>Title</b>	Prescribing of ulipristal acetate (Esmya) 5mg tablets
<b>References</b>	Cas alert March 2020: <a href="https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102997">https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102997</a>
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