Ulipristal acetate (Esmya) – reclassified as a RED drug

Thurrock CCG and Basildon and Brentwood CCG have reclassified ulipristal acetate (Esmya) as a red drug following MHRA advice issued in February and August 2018. Therefore ulipristal should NOT be initiated or prescribed by primary care.

Esmya® (Ulipristal acetate) is 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. This is a licensed indication and had been deemed suitable for prescribing in primary care after initiation by a specialist.

A request to the South West Essex Medicines Management Committee in September 2017 to extend the use as intermittent treatment for moderate to severe uterine fibroids in line with the product licence. This request was rejected by the SWEMMC.

Therefore before the MHRA advice ulipristal acetate was a yellow drug for the treatment of moderate uterine fibroids and it was not commissioned for intermittent treatment.

In December 2017, the European Medicines Agency started a safety review of Esmya® after it was reported that four cases of serious liver injury had occurred after its use. In three of the cases a liver transplant was needed. In February 2018, temporary safety measures were introduced whilst the review was ongoing following a further case of serious liver injury requiring liver transplant. The advice at that point was that that no new treatment courses should be prescribed until further notice. During treatment women needed to have liver function tests at least once a month. In addition, liver testing was required 2-4 weeks after stopping treatment.

A MHRA CAS alert in August 2018 stated that Esmya should not be used unless:

With immediate effect, Esmya should not be used unless:

- The new restricted indication is met (one course of pre operative treatment), and the patient does not have an underlying liver disorder; more than one treatment course is now authorised only in women who are not eligible for surgery (please note intermittent therapy is not commissioned in South West Essex)
- Liver function monitoring is performed before, during and after treatment courses
- The rare risk of liver damage and need for liver function monitoring have been discussed and the patient knows the signs and symptoms of liver injury and what to do if they occur.

Pharmacists should provide the new patient card to women when dispensing Esmya. See letter for how to obtain copies.

These restrictions replace the temporary safety measures, including no new patients to be prescribed Esmya, introduced in February 2018 while the review of the association between Esmya and liver damage was ongoing.

Due to the safety concerns and the restricted licenced indications this medication is no longer deemed suitable for primary care prescribing and has been reclassified as a RED drug.

Position Statement No.	39
Title	Esmya (ulipristal acetate) reclassified as a RED drug
Reference	1. CAS alert August 2018. Esmya (ulipristal acetate) for the symptoms of uterine fibroids: restrictions to use and requirement to check liver function before and after treatment. 2. CAS MHRA Dear Doctor letter August 2018: Esmya (ulipristal acetate) for uterine fibroids: monitor liver function in current and recent users and do not start treatment in new users or those between treatment courses 3. MHRA Drug Safety Update March 2018. Esmya (ulipristal acetate) for uterine fibroids: do not initiate or re start treatment; monitor liver function in current users 4. RCOG. August 2018. RCOG advice on Esmya (ulipristal acetate)
Acknowledgements	N/A
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Approved by	**Basildon and Brentwood CCG:** Prescribing Subgroup, Patient Quality and Safety Committee, Board **Thurrock CCG:** Medicines Management and Safety Group, Patient Quality and Safety Committee, Transformation and Sustainability Committee, Board **South West Essex Medicines Management Committee**
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