Ulipristal Acetate (Esyma®) for women with symptomatic uterine fibroids

Interim Position Statement for South East London

Key points of position statement

The MHRA wrote to health professionals on 9 February 2018 advising liver function in current and recent users of ulipristal acetate (Esyma®) should be monitored and treatment should not be initiated in new users or those between treatment courses [1]

Scenario	Secondary care action	Primary care action
Treatment naïve	Do not initiate ulipristal	NA, ulipristal should not be initiated in primary care
Mid treatment course (i.e. currently taking 5mg OD) or stopped treatment less than 4 weeks ago	• Responsible prescriber to perform LFT monitoring at least monthly during treatment and 2-4 weeks after stopping treatment • Responsible prescriber to stop treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. • If no LFT dysfunction is identified, patients may continue their course. Inform all women about the potential for hepatic toxicity, so they can make an informed decision with regards to continuation of medication in those with normal LFTs. • Advise all women of the signs or symptoms suggestive of liver injury† • Trusts and GPs to check transaminase levels immediately in current or recent users of ulipristal who present with signs or symptoms suggestive of liver injury†	
Completed ≥1 treatment courses and being considered for an additional course	Do not re-initiate ulipristal	Do not re-initiate ulipristal. If uterine fibroids require further management, refer patient back to the prescriber who initiated ulipristal.

† Signs or symptoms suggestive of liver injury: nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly on member CCG websites.

b) This Area Prescribing Committee position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS.

References

1. MHRA. Esmya (ulipristal acetate) for uterine fibroids: monitor liver function in current and recent users; do not initiate treatment in new users or those between treatment courses. (2018).

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

9 February 2018

Dear Healthcare Professional

Esmya (ulipristal acetate) for uterine fibroids: monitor liver function in current and recent users; do not initiate treatment in new users or those between treatment courses

I am writing to inform you of new temporary safety measures which have been introduced for Esmya following reports of serious liver injury in women using the medicine for uterine fibroids.

Summary

Five reports of serious liver injury, including four cases of hepatic failure needing liver transplantation, have been reported worldwide in women using Esmya for uterine fibroids. The following temporary safety measures have been introduced while an EU-wide review of the evidence is ongoing:

- Do not initiate new treatment courses of Esmya, including in women who have completed one or more treatment courses previously
- Perform liver function tests at least once a month in all women currently taking Esmya. Stop Esmya treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. Liver function tests should be repeated in all women 2 to 4 weeks after stopping treatment.
- Check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated.
- Advise women using Esmya on the signs and symptoms of liver injury.

We will provide further information as soon as this review is completed.

The emergency contraceptive ellaOne also contains ulipristal acetate (single-dose, 30mg). No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.

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Background

Esmya was first authorised in 2012 for intermittent or pre-operative treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age. Each treatment course of 5mg daily lasts for up to 3 months and may be repeated with breaks between each course.

Approximately 20,400 treatment courses of Esmya were dispensed in the UK between 1 October 2016 and 30 September 2017.[1] To date, we have received 1 suspected adverse drug reaction report of hepatitis with the use of Esmya in the UK.

An EU-wide review of Esmya was started in December 2017 following four reports of serious liver injury (in three cases necessitating liver transplantation) in women using the medicine. Further information about the ongoing review can be found here. The new temporary safety measures have been introduced pending completion of the review following receipt in February 2018 of a further report of hepatic failure requiring liver transplant with Esmya.

Call for reporting

Please report suspected adverse drug reactions to the MHRA through the Yellow Card Scheme: https://yellowcard.mhra.gov.uk/

Yours faithfully,

Sarah Branch *(Electronic signature)*

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[1] Data derived from IQVIA MIDAS 10/2016-09/2017 by MHRA, January 2018. The usage estimate is based on the assumption that each treatment course was of 3 months duration. The number of courses each woman takes may vary between 1 and 4 courses. The number of courses quoted is a broad estimation and is not therefore equivalent to the number of women who used Esmya.