Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

ULIPRISTAL (ESMYA®) FOR THE TREATMENT OF UTERINE FIBROIDS

NOT RECOMMENDED FOR PRESCRIBING – DOUBLE RED

Name: generic (trade)	What it is	Indication	Date decision last revised	Decision status	NICE / SMC Guidance
Ulipristal Acetate (Esmya®)	synthetic selective progesterone receptor modulator	treatment of moderate to severe symptoms of uterine fibroids	February 2019 (update March 2021 with revised MHRA Drug Safety Information)	Final	NICE guideline [NG88]– recommended for restricted use SMC - accepted for restricted use

Recommendation:

Ulipristal Acetate (Esmya®) is NOT RECOMMENDED for the treatment of uterine fibroids following the publication of the MHRA Drug Safety Updates (DSUs) (February 2021, March and August 2018):

- Following February 2021 DSU - The indication of ulipristal acetate 5mg for uterine fibroids was further restricted due to the risk of serious liver injury and liver failure, with some cases requiring liver transplantation.
- Previous DSU (March 2018) for Esmya® (ulipristal acetate) for uterine fibroids reported a link with cases of serious liver injury and recommended: *do not initiate or re-start treatment; monitor liver function in current and recent users.* There was subsequently a local 'not recommended for prescribing' recommendation. This DSU was superseded by an updated DSU August 2018.
- An EU review investigating the link between Esmya® and cases of serious liver injury concluded that Esmya® may have contributed to the development of some of the 8 cases of serious liver injury reported for this drug. The review recommended restricting the indicated population for Esmya® for safety reasons and introduced measures to minimise risk of liver injury. Following this an updated DSU (August 2018) was published with new restrictions to use and requirements for liver function monitoring before, during, and after treatment.
- The previous and updated DSU were discussed at the October 2018 and February 2019 HMMC meetings including feedback from local specialists. Concerns were raised about the risks associated with Esmya® including ongoing safety concerns, complexity of monitoring, potential interactions with other liver toxic drugs and that alternative treatment options are available.

  It is recommended that Esmya® should remain as 'double red' (not recommended for prescribing) and this is supported by local specialists at East and North Hertfordshire NHS Trust, West Hertfordshire Hospitals NHS Trust and Princess Alexandra Hospital Trust.
- The August 2018 DSU includes the following information:

ellaOne
The emergency contraceptive ellaOne also contains ulipristal acetate in a single dose of 30 mg. No cases of serious liver injury have been reported with ellaOne since it was authorised in the EU in 2009 and there are no concerns or changes to its use at this time.

Refer to following links for full details of DSUs:
February 2021: Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury - GOV.UK (www.gov.uk)
August 2018: https://www.gov.uk/drug-safety-update/esmya-ulipristal-acetate-and-risk-of-serious-

liver-injury-new-restrictions-to-use-and-requirements-for-liver-function-monitoring-before-during-and-after-treatment

March 2018: https://www.gov.uk/drug-safety-update/esmya-ulipristal-acetate-for-uterine-fibroids-do-not-initiate-or-re-start-treatment-monitor-liver-function-in-current-and-recent-users

Version	2.1 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include: • Rebadging with HWE ICB and removal of ENHCCG and HVCCG headers • Review date removed and replaced with standard statement.
Developed by	ENHCCG and HVCCG PMOT
Approved by	HMMC and WEMOPB
Date approved/updated	HMMC March 2021 and WEMOPB March 2018
Review date:	The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.
Superseded version	2.0