Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

**LICENCE AMENDED**
**Please refer to the European Medicines Agency website for further information**

# Final Appraisal Recommendation
# Advice No: 0716 – March 2016

## Ulipristal acetate (Esmya®) 5 mg tablets

## Submission by Gedeon Richter UK Ltd

### Recommendation of AWMSG

**Ulipristal acetate (Esmya®) is recommended as an option for use within NHS Wales for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.**

**Additional notes:**

- Please refer to the Summary of Product Characteristics (SPC) for the full licensed indication and monitoring requirements.
- This advice incorporates and replaces the AWMSG recommendation on ulipristal acetate for the pre-operative treatment of moderate to severe symptoms of uterine fibroids (Advice number 1913, originally published July 2013).
- This advice has been updated to align with the restriction made to the licence indication by the European Medicines Agency in February 2021.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2767), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by the Minister for Health and Social Services and will be considered for review every three years.

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| Marketing authorisation holder on first issue | Gedeon Richter (UK) Ltd |
| Date of first issue | March 2016 |
| Last reviewed | February 2021 |