

**FSRH CEU response to European Medicines Agency  
recommendations regarding use of ulipristal acetate for  
management of uterine fibroids – Use of ulipristal acetate for  
emergency contraception**

**12 February 2018**

The European Medicines Agency (EMA) is currently reviewing the safety of use of Esmya<sup>®</sup> (ulipristal acetate) for management of uterine fibroids. This review follows reports of a very small number of cases worldwide of serious liver injury in women using Esmya. Until the review process is complete, temporary restrictions have been placed on commencing treatment with Esmya and guidelines for monitoring liver function in women already taking Esmya have been introduced. The EMA recommendations are available at [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2018/02/news\\_detail\\_002902.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2018/02/news_detail_002902.jsp&mid=WC0b01ac058004d5c1)

Ulipristal acetate is also the active ingredient of the oral emergency contraceptive, ellaOne<sup>®</sup>. In comparison to Esmya, which is taken daily for several months, ellaOne is taken as a single dose on an occasional basis for emergency contraception. The EMA is clear that no cases of serious liver injury have been reported with ellaOne and there are no concerns regarding ellaOne at this time.

In line with this recommendation, the FSRH CEU reassures FSRH members that FSRH recommendations regarding use of ellaOne for contraception remain unchanged at this time. The FSRH Emergency Contraception guideline can be found at <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/>

*The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual and Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a member's enquiry service, evidence based guidance, new SRH product reviews and clinical audit/research. [Find out more here.](#)*