



Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit

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Faculty Statement from the CEU

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Frequently Asked Questions on Ulipristal Acetate (EllaOne®) Emergency Contraception

Ulipristal blocks the action of progesterone. Does this mean that it will reduce the efficacy of hormonal contraceptives?

Interactions with hormonal contraception have not been studied but ulipristal could in theory reduce the efficacy of progestogen-containing contraceptives. In line with the instructions in the manufacturer's Summary of Product Characteristics (SPC),¹ current advice for women using hormonal methods that induce bleeding (e.g. combined pill) is to use condoms or avoid unprotected sexual intercourse (UPSI) until their next bleed.

If a woman takes ulipristal while using a contraceptive method that induces amenorrhoea, for how long should additional contraception be used and when should a pregnancy test be performed?

As there are no specific instructions in the manufacturer's literature, advice on additional contraception and pregnancy testing is at the discretion of the treating clinician. The CEU has suggested advising the use of additional barrier contraception or avoidance of UPSI until pregnancy has been excluded. The minimum time before pregnancy can be excluded is approximately 3 weeks after UPSI, depending on the sensitivity of the pregnancy test (refer to pregnancy test kit for specific instructions).

The use of additional contraception for 3 weeks is probably overcautious, as ulipristal is virtually eliminated within 7 days of administration (half life 32.4 ± 6.3 hours). The CEU will review this recommendation when updating future guidance documents on hormonal methods and emergency contraception (EC).

When can a new method of contraception be started after taking ulipristal?

Currently the CEU would advise that women wait until their next menstrual period (or until pregnancy has been excluded by pregnancy testing) before starting a new contraceptive method. Barrier contraception should be used until then. This recommendation will also be reviewed in due course.

Can ulipristal be used more than once in the same cycle?

The manufacturer states that repeated administration of ulipristal within the same menstrual cycle is not advisable as the safety and efficacy have not been investigated.^{1,2}

Can ulipristal be used for multiple episodes of UPSI in the same cycle?

One or more episodes within previous 5 days

Ulipristal is effective and licensed for up to 120 hours after UPSI. Therefore, it can be used for multiple episodes of UPSI if all episodes have occurred within the last 120 hours.

One episode within and one or more episodes over 5 days since UPSI

There are currently no data on the efficacy of ulipristal in women who have had UPSI more than 120 hours before presenting for EC.¹ As there may be a risk of pregnancy from the first episode of UPSI, ulipristal should not be administered unless the first episode was more than 21 days ago and a pregnancy test is negative.

Is ulipristal suitable for women who are breastfeeding?

It is not known whether ulipristal is excreted in breast milk so breastfeeding women are advised not to breastfeed and to discard expressed milk for 36 hours after treatment.^{1,2}

Can ulipristal be supplied by Patient Group Direction?

Yes, it is legally possible to supply ulipristal by Patient Group Direction (PGD). Ulipristal is currently a Black Triangle Drug (i.e. a recently licensed drug that is subject to special reporting arrangements for adverse drug reactions). Use of such drugs should be justified by best clinical practice and the PGD should clearly describe the status of the product.³ Efficacy data suggest that use of ulipristal is justifiable in women who decline the emergency intrauterine device (IUD), particularly if presenting between 72 to 120 hours after UPSI when no other emergency contraceptive is licensed and the efficacy of progestogen-only EC is known to be reducing.

More detailed information can be found in the manufacturer's SPC¹ and the FSRH Clinical Effectiveness Unit's new product review of ulipristal.²

References

- 1 HRA Pharma UK Ltd. EllaOne 30 mg: Summary of Product Characteristics (SPC). 2009.
<http://www.emc.medicines.org.uk/medicine/22280/SPC/ellaOne+30+mg/>.
- 2 Faculty of Sexual and Reproductive Health Care. New Product Review (October 2009): Ulipristal Acetate (ellaOne®). 2009.
http://www.ffprhc.org.uk/admin/uploads/42_ellaOneNewProductReview1009.pdf.
- 3 Royal College of Nursing (RCN). Patient Group Directions: Guidance and Information for Nurses. London, UK: RCN: 2004.
http://www.rcn.org.uk/_data/assets/pdf_file/0008/78506/001370.pdf.