

Family Planning Alliance Australia (FPAA) statement – Ulipristal Acetate Emergency Contraception and Breastfeeding

Ulipristal acetate emergency contraception (UPA EC) is administered as a single 30 mg oral dose within 5 days of unprotected intercourse. The Product Information and some contraceptive guidelines recommend expressing and discarding breastmilk for 7 days after administration. (1, 2) However, other guidelines recommend a 24 hour time frame, based on the rapidly declining levels of UPA excreted in breast milk 24 hours after a 30 mg dose. (3)

Pharmacokinetics

UPA is rapidly absorbed with a peak plasma concentration occurring approximately 1 hour following oral administration and a half-life of approximately 32 hours.(1)

Lactation

An unpublished study, quoted in international product information, examined the pharmacokinetics of excretion of UPA and its active metabolite monodemethyl-UPA in the breast milk of 12 lactating women, after an oral dose (assumed to be 30 mg). The mean daily total concentrations of active drug in breast milk were 27.19 mcg/L (0-24 hours), 3.58 mcg/L (24-48 hours), 1.84 mcg/L (48-72 hours), 1.21 mcg/L (72-96 hours) and 0.79 mcg/L (96-120 hours) in breast milk. This would equate to a fully breastfed infant receiving about 4.1 mcg/kg of drug plus active metabolite on the first day and a total of 5.2 mcg/kg over 5 days. Assuming a maternal weight of 60 kg, the infant would receive a weight-adjusted dosage of 0.8% of drug plus active metabolite on the first day and a total of 1% of the maternal dose over the 5-day period. (4)

Studies in infants

There are no studies in infants on the metabolism of UPA or the effect of UPA in breast milk.

Other considerations

Cessation of breast feeding

Cessation of breastfeeding for even short periods of time can be distressing to mothers and infants and may contribute to complete cessation of lactation.

Age of the infant

Infants aged under 2 months, and particularly those aged under 1 month, are the most susceptible to severe acute drug interactions.(5)

When ulipristal is the preferred method of EC

While the copper IUD is the most effective method of emergency contraception and has the advantage of providing ongoing protection from pregnancy, (6, 7) insertion may be unavailable or acceptable. Ulipristal is likely to be more effective than levonorgestrel EC,



particularly if unprotected intercourse has occurred between 96 and 120 hours ago, the BMI is>26 kg/m² or weight is >70 kg. (2, 8-10).

Use of similar drugs in breastfeeding

UPA and mifepristone are biologically similar selective progesterone receptor modulators methods of emergency contraception. Mifepristone is used for medical abortion at a much larger dose than the dose used for emergency contraception (200mg versus 30mg). Mifepristone has been shown to be excreted in breast milk in low levels (11) and international guidelines allow for uninterrupted breast feeding in those undergoing a medical abortion. (12)

Conclusion

Either insertion of a copper IUD or levonorgestrel 1.5 mg emergency contraceptive pill are the recommended methods of emergency contraception during lactation.

Where on balance UPA EC is considered the best option, breastfeeding can be continued uninterrupted, as the risk to the infant is low. For those wishing to avoid the highest infant exposure breast milk can be expressed and discarded for 24 hours after taking UPA EC.

Note that these recommendations are off-label but are supported by expert national and international opinion and clinical practice. (13)

- 1. EllaOne (ulipristal acetate) Australian approved product information. MS Health Pty Ltd., 01 September 2017.
- 2. FSRH Guideline Emergency Contraception: Faculty of Sexual & Reproductive Healthcare Statement. Clinical Effectiveness Unit; 2017 [cited 2018 23 October]. March 2017:[Available from: https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/.
- 3. Curtis KM, Tepper NK, Jatlaoui TC, Berry-Bibee E, Horton LG, Zapata LB, et al. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR Recomm Rep. 2016;65(3):1-103.
- 4. Ella (ulipristal acetate) United States of America approved product information. Afaxys Pharma LLC., 08 June 2018.
- 5. Anderson PO, Manoguerra AS, Valdes V. A Review of Adverse Reactions in Infants From Medications in Breastmilk. Clin Pediatr (Phila). 2016;55(3):236-44.
- 6. Turok DK, Jacobson JC, Dermish AI, Simonsen SE, Gurtcheff S, McFadden M, et al. Emergency contraception with a copper IUD or oral levonorgestrel: an observational study of 1-year pregnancy rates. Contraception. 2014;89(3):222-8.
- 7. Wu S, Godfrey EM, Wojdyla D, Dong J, Cong J, Wang C, et al. Copper T380A intrauterine device for emergency contraception: a prospective, multicentre, cohort clinical trial. BJOG. 2010;117(10):1205-10.
- 8. Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet. 2010.



- 9. Natavio M, Stanczyk FZ, Molins EAG, Nelson A, Jusko WJ. Pharmacokinetics of the 1.5mg levonorgestrel emergency contraceptive in women with normal, obese and extremely obese body mass index. Contraception. 2019.
- 10. Praditpan P, Hamouie A, Basaraba CN, Nandakumar R, Cremers S, Davis AR, et al. Pharmacokinetics of levonorgestrel and ulipristal acetate emergency contraception in women with normal and obese body mass index. Contraception. 2017;95(5):464-9.
- 11. Saav I, Fiala C, Hamalainen JM, Heikinheimo O, Gemzell-Danielsson K. Medical abortion in lactating women--low levels of mifepristone in breast milk. Acta Obstet Gynecol Scand. 2010;89(5):618-22.
- 12. Medical abortion: The Abortion pill up to 10 weeks: British Pregnancy Advisory Service; 2019 [cited 2019 9 April]. Available from: https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill-up-to-10-weeks/.
- 13. Emergency contraception and breast-feeding: Specialist Pharmacy Service. NHS; 2015 [updated 4 March 2016; cited 2019 9 April]. Available from: https://www.sps.nhs.uk/articles/emergency-contraception-and-breast-feeding/.