FSRH The Faculty of Sexual & Reproductive Healthcare

FSRH Statement: Ulipristal Acetate and Breastfeeding

January 2025

Recommendation

No interruption of breastfeeding is necessary following a single dose of Ulipristal Acetate when given for Emergency Contraception.

Following a review of the current recommendation, which states that breast milk should be expressed and discarded for one week after Ulipristal Acetate (UPA) (1), members of the Guideline Development Group (GDG) for the FSRH Guideline Emergency Contraception (EC) have agreed a recommendation that there is no need to avoid breastfeeding after taking a single dose of UPA-EC. This is in line with recommendations from the UK Drugs in Lactation Advisory Service (UKDILAS), which are published on the Specialist Pharmacy Service website (2).

The evidence

The published evidence is limited to one pharmacokinetic study (3). There is no published evidence relating to the effect of UPA-EC on the infants of breastfeeding women, including no published evidence of any harm.

The breast milk of 12 lactating women was collected in 24-hour increments after administration of UPA (dose not specified, but presumably 30mg). Concentrations of UPA in breast milk were measured and amounts were found to be negligible (table 1).

Hours since administration	Mean daily concentrations of ulipristal acetate (mcg/L)	Mean daily concentrations of monodemethyl-ulipristal acetate (mcg/L)
0 - 24	22.7	4.49
24 - 48	2.96	0.62
48 - 72	1.56	0.28
72 - 96	1.04	0.17
96 - 120	0.69	0.10

Table 1. Mean daily concentrations of uliprisal acetate and its active metabolite, monodemethyl-ulipristal acetate in breast milk (3).

Expert advice from UKDILAS

Given the lack of evidence, the GDG heard expert testimony from UKDILAS. In their decision making, UKDILAS looked beyond the pharmacokinetic data and considered the likely effect on the infant taking into consideration drug toxicity, oral absorption and dosing regimen. This was weighed against the known benefits of breastfeeding and the implications of asking individuals to withhold breastfeeding.

UKDILAS discussed the very limited evidence showing negligible amounts of UPA and its metabolite in breast milk (3). As an example, a fully breastfed two-month-old infant would receive approximately 0.03mg over five days, which is 0.09% of the total maternal dose. In the study, breast milk was not given to the breastfed infants so infant outcomes and infant plasma levels were not reported.

The risk of infant adverse effects is considered extremely low given that UPA is of low toxicity (4). Additionally, common side effects associated with a single dose of UPA are non-serious and reversible (5). To date, there is no published evidence of any harm to the infant following a single dose of UPA-EC. The benefits of breastfeeding, to the women and the infant, are well established. Withholding breastfeeding for a prolonged period can impact the lactation process and is often impractical, frequently leading to breastfeeding discontinuation.

Additional considerations

Side effects are not expected in the infant following a single dose of UPA (2). As with any medication given to an individual who is breastfeeding, as a precaution the caregiver should monitor the infant following a single dose of UPA-EC (2).

The choice of EC should be made on an individual basis taking the following into account

- Individual preference following an informed discussion of options
- The Cu-IUD is the most effective method of EC (1)
- Breastfeeding individuals have a higher relative risk of uterine perforation during insertion of intrauterine contraception than non-breastfeeding women. The absolute risk of perforation is low (1)
- EC is only required from day 21 after childbirth (1)
- EC is not required if criteria for the lactational amenorrhoea method (LAM) are fully met (1,6)
    - Fully breastfeeding
    - Amenorrhoeic
    - Less than six months postpartum
- The individual's requirement to immediately start an ongoing method of contraception
    - Following a single dose of UPA-EC, wait five days before starting a hormonal method of contraception (1)
- The effectiveness of LNG-EC could be reduced in individuals with BMI >26 kg/m^2 or weight >70 kg (1)
        - Consider double-dose (3 mg) LNG
        - or UPA-EC

References

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3. Afaxys Inc. Ella Package Insert. January 27, 2020. [Accessed from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf]
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6. FSRH Clinical Guideline: Contraception after Pregnancy (2017, amended 2020). Available at FSRH Clinical Guideline: Contraception After Pregnancy (January 2017, amended October 2020) | FSRH [accessed 7/1/25]