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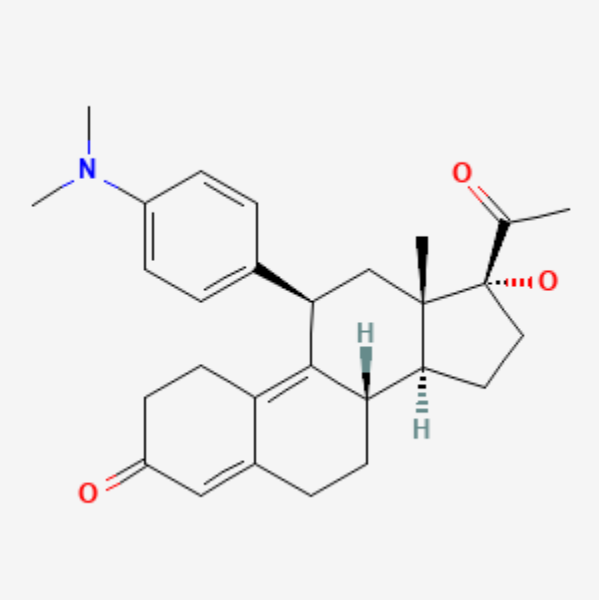
Ulipristal

Revised: July 18, 2022.

CASRN: 159811-51-5



Drug Levels and Effects

Summary of Use during Lactation

Ulipristal is a selective progesterone receptor modulator used in a single dose as an emergency postcoital contraceptive. No information is available on the clinical use of ulipristal during breastfeeding; however, amounts in milk are low. If ulipristal is required by the mother, it is not a reason to discontinue breastfeeding. Some older sources recommend withholding breastfeeding for 24 hours after a dose,[1] but this is no longer a requirement according to current FDA-approved labeling.

Drug Levels

Ulipristal acetate is metabolized to mono- and di-demethylated metabolites by CYP3A4. Monodemethyl-ulipristal is pharmacologically active.

Maternal Levels. The breastmilk of 12 lactating women following administration of ulipristal (dosage not stated, but presumably 30 mg) was collected in 24-hour increments to measure the concentrations of ulipristal acetate and monodemethyl-ulipristal acetate in breastmilk. The mean daily concentrations of ulipristal acetate in breastmilk were 22.7 mcg/L (0 to 24 hours), 2.96 mcg/L (24 to 48 hours), 1.56 mcg/L (48 to 72 hours), 1.04 mcg/L (72 to 96 hours), and 0.69 mcg/L (96 to 120 hours). The mean daily concentrations of monodemethyl-ulipristal acetate in breastmilk were 4.49 mcg/L (0 to 24 hours), 0.62 mcg/L (24 to 48 hours), 0.28 mcg/L (48 to 72 hours), 0.17 mcg/L (72 to 96 hours), and 0.10 mcg/L (96 to 120 hours). Using these data, a fully breastfed infant would receive 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).[2] Assuming a 30 mg dose and an average 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.

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

Relevant published information was not found as of the revision date.

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

Alternate Drugs to Consider

Intrauterine Copper Contraceptive, Oral Levonorgestrel

References

1. Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep. 2016;65:1–66. PubMed PMID: 27467319.
2. Afaxys Inc. Ella Package Insert. January 27, 2020.

Substance Identification

Substance Name

Ulipristal

CAS Registry Number

159811-51-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Contraceptive Agents

Contraceptives, Postcoital

Contraceptive Agents, Female