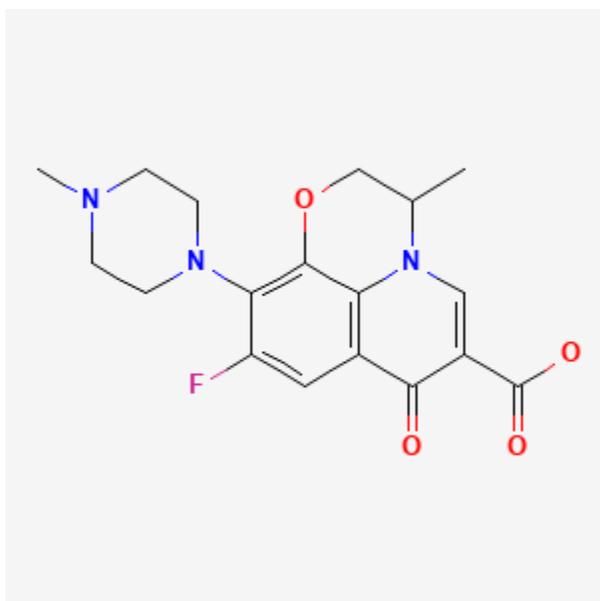




Ofloxacin

Revised: February 15, 2021.

CASRN: 82419-36-1



Drug Levels and Effects

Summary of Use during Lactation

Ofloxacin appears in breastmilk in low levels. Fluoroquinolones have traditionally not been used in infants because of concern about adverse effects on the infants' developing joints. However, recent studies indicate little risk.[1,2] The calcium in milk might prevent absorption of the small amounts of fluoroquinolones in milk.[3] Insufficient data exist to prove or disprove this assertion. Developmental problems have been reported in two infants exposed to ofloxacin in breastmilk, but their mothers were also exposed to several drugs during pregnancy and during breastfeeding, so the problems cannot necessarily be attributed to ofloxacin. Use of ofloxacin is acceptable in nursing mothers with monitoring of the infant for possible effects on the flora, such as diarrhea or candidiasis (thrush, diaper rash). . Avoiding breastfeeding for 4 to 6 hours after a dose should decrease the exposure of the infant to ofloxacin in breastmilk.

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Maternal use of an ear drop or eye drop that contains ofloxacin presents negligible risk for the nursing infant. To substantially diminish the amount of drug that reaches the breastmilk after using eye drops, place pressure over the tear duct by the corner of the eye for 1 minute or more, then remove the excess solution with an absorbent tissue.

Drug Levels

Maternal Levels. Ten lactating women (time postpartum not stated) were given ofloxacin 400 mg orally every 12 hours for 3 doses. Milk ofloxacin was measured after the third dose. The highest levels averaging 2.41 mg/L occurred 2 hours after the dose. Average milk levels then fell as follows: 1.91 mg/L at 4 hours; 1.25 mg/L at 6 hours; 0.64 mg/L at 9 hours; 0.29 mg/L at 12 hours; and 0.05 mg/L at 24 hours after the dose.[4] Using the peak milk level data from this study, an exclusively breastfed infant would receive an estimated maximum of 0.36 mg/kg daily with this maternal dosage regimen.

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

Effects in Breastfed Infants

Ofloxacin was used as part of multidrug regimens to treat two pregnant women with multidrug-resistant tuberculosis, one throughout pregnancy and postpartum and the other postpartum only. The infants were breastfed (extent and duration not stated). At age 4.6 and 5.1 years, the children were developing normally except for a mild speech delay in one and hyperactivity in the other.[5]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Systemic, Ophthalmic) Ciprofloxacin, [Levofloxacin](#)

References

1. Gürpınar AN, Balkan E, Kiliç N, et al. The effects of a fluoroquinolone on the growth and development of infants. *J Int Med Res.* 1997;25:302–6. PubMed PMID: 9364293.
2. van den Oever HL, Versteegh FG, Thewessen EA, et al. Ciprofloxacin in preterm neonates: Case report and review of the literature. *Eur J Pediatr.* 1998;157:843–5. PubMed PMID: 9809826.
3. Fleiss PM. The effect of maternal medications on breast-feeding infants. *J Hum Lact* 1992;8:7. Letter. PMID: 1558663
4. Giamarellou H, Kolokythas E, Petrikos G, et al. Pharmacokinetics of three newer quinolones in pregnant and lactating women. *Am J Med.* 1989;87 Suppl 5A:49S–51S. PubMed PMID: 2589384.
5. Drobac PC, del Castillo H, Sweetland A, et al. Treatment of multidrug-resistant tuberculosis during pregnancy: long-term follow-up of 6 children with intrauterine exposure to second-line agents. *Clin Infect Dis.* 2005;40:1689–92. PubMed PMID: 15889370.

Substance Identification

Substance Name

Ofloxacin

CAS Registry Number

82419-36-1

Drug Class

Breast Feeding

Lactation

Anti-Infective Agents

Antibacterial Agents

Quinolones

Fluoroquinolones