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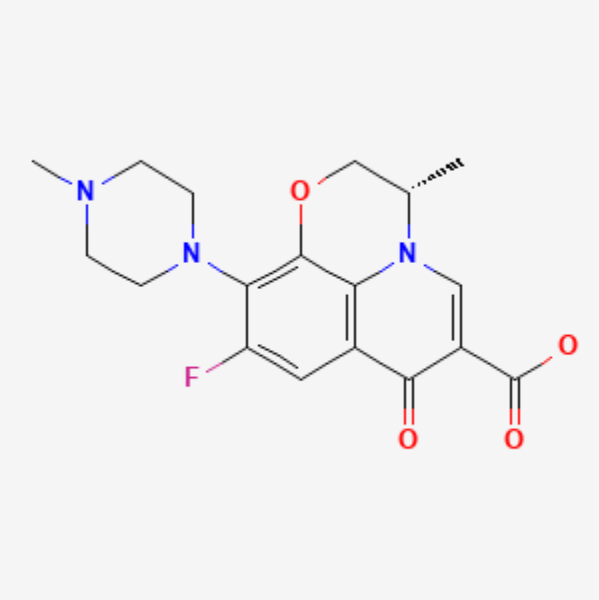
Levofloxacin

Revised: June 21, 2021.

CASRN: 100986-85-4



Drug Levels and Effects

Summary of Use during Lactation

Levofloxacin is the *S*-enantiomer of the fluoroquinolone, ofloxacin. No information is available on the clinical use of levofloxacin during breastfeeding. However, amounts in breastmilk appear to be far lower than the infant dose and would not be expected to cause any adverse effects in breastfed infants. Fluoroquinolones such as levofloxacin have traditionally not been used in infants because of concern about adverse effects on the infants' developing joints. However, more recent studies indicate little risk.[1,2] The calcium in milk might prevent absorption of the small amounts of fluoroquinolones in milk,[3] but insufficient data exist to prove or disprove this assertion. Use of levofloxacin is acceptable in nursing mothers with monitoring of the infant for possible effects on the gastrointestinal 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 levofloxacin in breastmilk. Maternal use of an eye drop that contains levofloxacin presents negligible risk for the nursing infant.

Drug Levels

Maternal Levels. Ten lactating women (time postpartum not stated) were given the racemic mixture, ofloxacin, 400 mg orally every 12 hours for 3 doses. Milk ofloxacin was measured after the third dose. The highest levels averaging 2.4 mg/L occurred 2 hours after the dose. Average milk levels then fell as follows: 1.9 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.

One woman was given levofloxacin 500 mg daily intravenously for 9 days, then orally for 17 days. Twenty-six breastmilk samples were obtained beginning on day 10 of therapy and continued for 6 days after the discontinuation of therapy. A pharmacokinetic model that was developed predicted that a peak milk level of 8.2 mg/L would occur 5 hours after the dose. The milk levels fell with an estimated half-life of 7 hours. Traces of levofloxacin were still detectable in breastmilk 65 hours after the dose. The authors calculated that an exclusively breastfed infant whose mother was taking 500 mg daily would receive 1.25 mg daily in breastmilk, which is far below the dose of levofloxacin used in children.[5]

Two nursing mothers each took one 500 mg capsule of levofloxacin (Tavanic-Sanofi, Istanbul) orally. Eleven complete collections of breastmilk were taken over the following 24 hours. Peak levofloxacin milk levels of 265 and 258 mcg/L occurred at 2.5 and 3 hours, respectively, in the two mothers. Average milk levels were 101 and 105, mcg/L, respectively. The half-lives in milk were 4.95 and 5.33 hours, respectively.[6] Using the average milk levels, a fully breastfed infant would receive an average of 15.5 mcg/kg daily.

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

(Systemic) Ciprofloxacin; (Ophthalmic) Ciprofloxacin, Ofloxacin

References

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4. Giamarellou H, Kolokythas E, Petrikkos 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.
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Substance Identification

Substance Name

Levofloxacin

CAS Registry Number

100986-85-4

Drug Class

Breast Feeding

Lactation

Anti-Infective Agents

Antibacterial Agents

Quinolones

Fluoroquinolones