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Diclofenac

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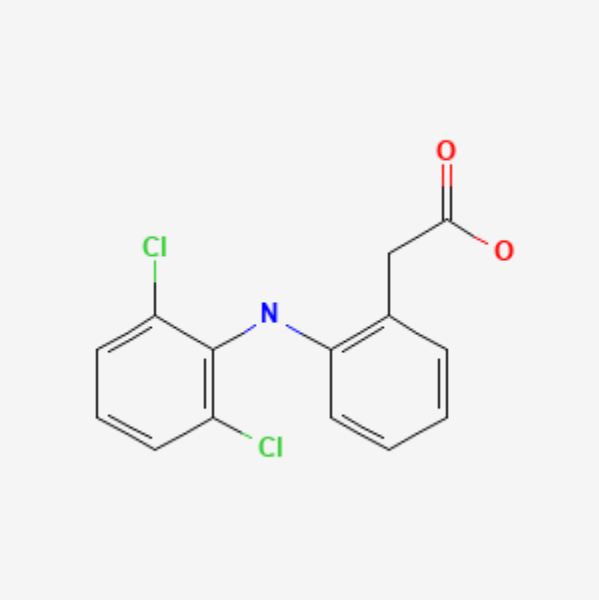
CASRN: 15307-86-5



Drug Levels and Effects

Summary of Use during Lactation

Data on excretion of diclofenac into milk are poor, but the drug has a short half-life and little glucuronide metabolite formation. Levels in milk appear to be quite low. Most reviewers consider diclofenac to be acceptable during breastfeeding.[1-5] Other agents having more published information may be preferred, especially while nursing a newborn or preterm infant.[6]

Maternal use of diclofenac topical gel or eye drops would not be expected to cause any adverse effects in breastfed infants. 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.

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Diclofenac was undetectable (<100 mcg/L) in the breastmilk over a 6-hour period after a 50 mg intramuscular injection in 6 women.[7]

Six mothers were given oral diclofenac 100 mg daily for one week postpartum. The drug was undetectable (<10 mcg/L) in milk of any of 59 samples of milk collected (collection times unspecified).[7]

A woman treated with 150 mg daily of diclofenac had a breastmilk diclofenac level of 100 mcg/L, equivalent to about 0.03 mg/kg daily for the infant.[8]

Fifteen women taking diclofenac 25 mg orally (n = 11) or a 50 mg suppositories (n = 4) for postpartum pain donated a total of 20 milk samples for analysis at random times at 5 to 6 days postpartum. Nine of the women taking oral diclofenac had undetectable (<0.5 mcg/L) milk concentrations at times ranging from 2 to 64 hours after a dose. Milk levels from 0.84 to 3.89 mcg/L were found in 4 milk samples at times ranging from 3 to 10 hours after a dose. In the 4 women taking a 50 mg suppository, 3 milk diclofenac levels ranged from 0.56 to 1.63 mcg/L at times ranging from 7 to 16.5 hours after a dose. In one woman, diclofenac was undetectable in milk 54 hours after a dose.[9] Note that this paper does not state the number of doses taken prior to sampling, so steady-state is not guaranteed. The pharmacokinetic analysis of samples was performed in an invalid way, and pharmacokinetic parameters reported in the paper are therefore not valid.

Effects in Breastfed Infants

In one study, 30 mothers undergoing elective cesarean section were allowed to use 25 mg diclofenac suppositories along with either spinal or spinal and epidural anesthesia with a local anesthetic after delivery. The spinal anesthetic group used an average of 56 mg of diclofenac on the day of delivery and 33 mg on the next day whereas the women receiving both spinal and epidural anesthesia used 21 and 18 mg. No mention was made of adverse effects on the breastfed infants.[10]

A breastfed infant developed urticaria on day 15 of life. Her mother had been taking diclofenac (dosage unspecified) for pain since her cesarean section delivery. Diclofenac is a possible cause of the urticaria; however, the infant had also received hepatitis B vaccination 7 days before and the authors thought that it was a more likely cause of the reaction.[11]

A trial in women who received a cesarean section randomized participants to receive 2 tablets of acetaminophen 325 mg and tramadol 35.5 mg (Zaldiar, Gruenthal, Israel) every 6 hours as well as diclofenac 100 mg at 12, 24 and 48 hours after arrival in the maternity ward, either as a fixed dose or the same drugs on demand. No differences were noted in neonatal outcomes of peak bilirubin, need for phototherapy, and adverse effects, including irritability or altered consciousness. No adverse infant effects were seen.[12]

Effects on Lactation and Breastmilk

A trial in women who received a cesarean section randomized participants to receive 2 tablets of acetaminophen 325 mg and tramadol 35.5 mg (Zaldiar, Gruenthal, Israel) every 6 hours as well as diclofenac 100 mg at 12, 24 and 48 hours after arrival in the maternity ward, either as a fixed dose or the same drugs on demand. Patients on the fixed dose regimen had more breastfeeds (23.8 vs 19.2) and fewer instances of formula (8.2 vs 11.9) than the on demand group.[12]

A randomized, double-blind study was performed in pregnant women scheduled for cesarean section under spinal anesthesia with bupivacaine and fentanyl. Patients received either 100 mg diclofenac (n = 100), 100 mg tramadol (n = 100) or placebo (glycerin suppositories) n = 100, all given as rectal suppositories every 8 hours for the first 24 hours after surgery. The time to initiate breastfeeding was significantly shorter among mothers who received diclofenac than a placebo, 1.5 vs 4.1 hours with breastfeeding support and 3.5 vs 6.2 hours without

support. Diclofenac was slightly more effective than tramadol among mothers who received no support (3.5 vs 3.7 hours).[13]

Alternate Drugs to Consider

(Systemic) Acetaminophen, Celecoxib, Flurbiprofen, Ibuprofen, Indomethacin, Naproxen, Piroxicam

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Substance Identification

Substance Name

Diclofenac

CAS Registry Number

15307-86-5

Drug Class

Breast Feeding

Lactation

Milk, Human

Analgesic Agents

Anti-inflammatory Agents, Nonsteroidal