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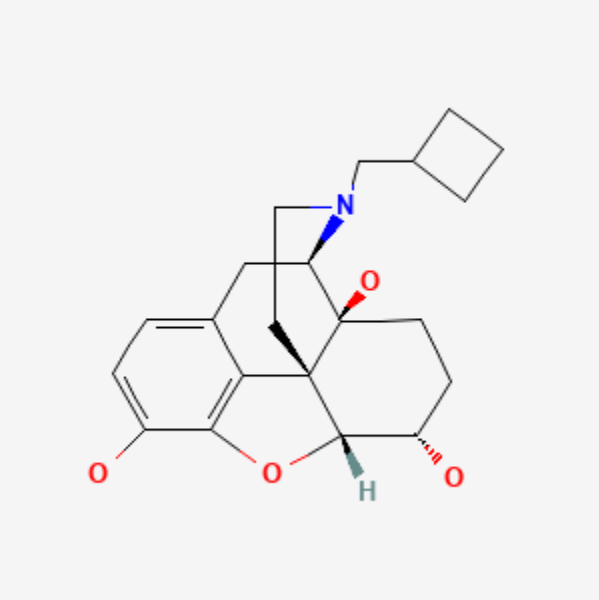
Nalbuphine

Revised: April 15, 2024.

CASRN: 20594-83-6



Drug Levels and Effects

Summary of Use during Lactation

Nalbuphine is excreted into breastmilk in amounts much smaller than the dose given to infants for analgesia. Because nalbuphine has poor oral absorption, it is unlikely to adversely affect the breastfed infant. If nalbuphine is required by the mother of a newborn, it is not a reason to discontinue breastfeeding; however, once the mother's milk comes in, it is best to provide pain control with a nonnarcotic analgesic and limit maternal intake to 2 to 3 days with close infant monitoring. If the baby shows signs of increased sleepiness (more than usual), difficulty breastfeeding, breathing difficulties, or limpness, a physician should be contacted immediately.

Drug Levels

In adults, nalbuphine has very poor oral bioavailability and is metabolized to inactive metabolites. Parenteral doses of 75 to 300 mcg/kg are used in infant and children. Nalbuphine sebacate is a nalbuphine prodrug that undergoes a prolonged release into the bloodstream where it is rapidly converted into nalbuphine.

Maternal Levels.

Seven women who were 3 to 7 days postpartum received a single 20 mg IM dose of nalbuphine. Milk samples were collected several times beginning at 1 hour and finishing at 24 hours after the dose. The half-life of elimination from milk was about 8 hours. A reported peak milk level in one mother was about 25 mcg/L and it occurred 1 hour after the dose. The average milk level over the 24 hour study period in all 7 mothers was about 5 mcg/L (range 1.5 to 20 mcg/L).[1] Using the peak level reported in this study, an exclusively breastfed infant would receive a dosage of 3.7 mcg/kg daily, equivalent to 1.1% of the maternal weight-adjusted dosage. Using the average milk level from this study, an exclusively breastfed infant would ingest 0.75 mcg/kg daily, equivalent to 0.2% of the maternal weight-adjusted dosage or 0.25 to 1% of the infant parenteral dosage.

Eighteen women were administered nalbuphine 0.2 mg/kg intravenously every 4 hours (average 25.5 mcg/kg daily) for pain following cesarean section. Milk samples were collected every 3 hours during the second day of drug administration. Because of small milk volumes, only 32 samples from 14 of the women were collected. The average milk nalbuphine concentration was 42 mcg/L, and the average maximum milk concentration was 61 mcg/L. The authors estimated that a fully breastfed infant would receive an average of 7 mcg/kg daily which amounts to about 0.6% of the weight-adjusted maternal dosage.[2]

Sixteen women who had undergone a cesarean section were administered one dose of 150 mg of nalbuphine sebecate intramuscularly and pooled milk samples were collected from each breast every 12 hours for 5 days. Dinalbuphine sebecate was undetectable (<0.1 mcg/L) in all samples. Of 73 milk samples collected, 52 had detectable nalbuphine (>0.1 mcg/L) concentrations. Most of the milk samples were collected between 48 and 108 hours after dinalbuphine sebacate administration and were less than 3 mL. The geometric mean peak nalbuphine concentration was 12.7 mcg/L at 77 hours after the dose. The median peak concentration was 9.3 mcg/L at 66 hours after the dose. The geometric mean nalbuphine concentration was 10.6 mcg/L. The mean measured daily infant dose of nalbuphine calculated by multiplying the concentration times the milk volume at each collection was 7.5 ng/kg with a median value of 8 ng/kg.[3]

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

Nalbuphine can increase serum prolactin.[4] However, the prolactin level in a mother with established lactation may not affect her ability to breastfeed.

A study compared women who received nalbuphine or butorphanol during labor (n = 26) to those who received no analgesia (n = 22). The time to effective breastfeeding was longer (46.5 minutes) in the analgesia group than in the no analgesia group (35.4 minutes).[5]

A national survey of women and their infants from late pregnancy through 12 months postpartum compared the time of lactogenesis II in mothers who did and did not receive pain medication during labor. Categories of medication were spinal or epidural only, spinal or epidural plus another medication, and other pain medication only. Women who received medications from any of the categories had about twice the risk of having delayed lactogenesis II (>72 hours) compared to women who received no labor pain medication.[6]

Alternate Drugs to Consider

Acetaminophen, Butorphanol, Hydromorphone, Ibuprofen, Morphine

References

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Substance Identification

Substance Name

Nalbuphine

CAS Registry Number

20594-83-6

Drug Class

Breast Feeding

Lactation

Milk, Human

Analgesics, Opioid

Narcotics

Narcotic Antagonists