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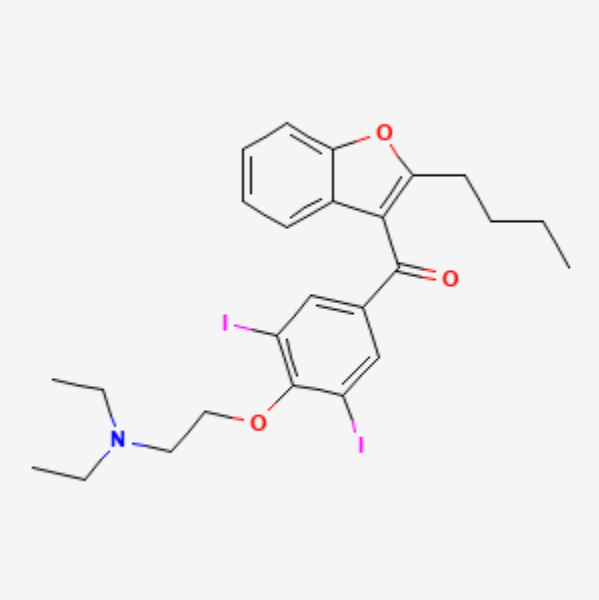
NLM Citation: Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Amiodarone. [Updated 2021 Jan 18].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Amiodarone

Revised: January 18, 2021.

CASRN: 1951-25-3



Drug Levels and Effects

Summary of Use during Lactation

Breastmilk and infant serum levels of amiodarone and its active metabolite are somewhat unpredictable, but can be high during breastfeeding. The infant receives an estimated dose of amiodarone plus desethylamiodarone ranging from 3.5 to 45% of the mother's weight-adjusted amiodarone dose, with a median dose of about 11%.[1-4] Infant serum levels of the drug plus metabolite range from 14 to 74% of simultaneous maternal levels, with the higher values reflecting transplacental passage of the drug.[2-4] In addition to possible cardiac effects, these compounds contain a large amount of iodine which may be released during metabolism. Thyroid dysfunction was reported in one breastfed infant. Even if the drug were discontinued at birth, the mother would continue to excrete amiodarone and its metabolite (and possibly large amounts of iodine) into breastmilk for days to weeks.

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Some investigators believe that breastfeeding can be undertaken during maternal amiodarone use with periodic monitoring of infant cardiac and thyroid function status,[5,6] especially if only a single dose of amiodarone is given.[7,8] Infant serum levels of amiodarone and desethylamiodarone may be useful for ruling out cardiac effects of the drug. If hypothyroidism develops, therapy should be promptly initiated.

Drug Levels

Amiodarone is an iodine-containing compound that is active and is also metabolized to the active metabolite desethylamiodarone. Metabolism also releases 6 mg of free iodine for each 100 mg of amiodarone which can affect thyroid function. The drug has an exceptionally long half-life of 100 days in adults because of extensive storage in body fat. It requires weeks to months to attain steady state and to be cleared from the body.[6]

Maternal Levels. After having taken amiodarone 200 mg twice daily 5 days weekly for 4 years, the milk of a mother was completely expressed 4 times during the first 2 days postpartum. The average milk amiodarone concentration was 3.5 mg/L. The authors calculated that her infant would have received an average of 18% and a maximum of 26% of the maternal weight-adjusted dosage of amiodarone.[9]

A woman who took amiodarone with reducing doses of 600, 400 and 200 mg daily for one week at each dosage level during the last 3 weeks of pregnancy had milk amiodarone and desethylamiodarone levels of 0.5 to 1.8 mg/L and 0.4 to 0.8 mg/L, respectively, in 5 samples of colostrum obtained during days 2 and 3 postpartum.[1]

In a mother who took amiodarone 200 mg daily for the last 5 weeks of pregnancy and for one week after delivery, milk amiodarone and desethylamiodarone levels were 0.55 and 0.44 mg/L, respectively, at 4 weeks postpartum and 0.030 and 0.002 mg/L at 6 weeks postpartum.[4]

A mother who took amiodarone 200 mg daily throughout pregnancy and during breastfeeding had milk amiodarone and desethylamiodarone levels of 1.7 and 0.75 mg/L, respectively, 2 weeks postpartum and 3.0 and 1.8 mg/L 3 weeks postpartum.[4]

Another mother who took amiodarone 200 mg daily throughout pregnancy had milk amiodarone and desethylamiodarone levels of 2.2 and 0.77 mg/L, respectively, at birth. Her infant was breastfed, but no infant serum levels were measured.[4]

A woman who took amiodarone 400 mg daily from week 14 of pregnancy and throughout nursing had milk amiodarone levels that varied from 1.06 to 3.65 mg/L (average 2.52 mg/L) and milk desethylamiodarone levels that varied from 0.5 to 1.24 mg/L (average 0.9 mg/L) on 5 occasions during the month following delivery. Her breastfed infant's thyroid function tests remained normal.[3]

A woman who took amiodarone 800 mg daily for 1 week starting at week 34 of pregnancy, then 400 mg daily for the rest of her pregnancy and during breastfeeding had milk amiodarone levels that varied from 3.6 to 14.4 mg/L (average 10.4 mg/L) and milk desethylamiodarone levels that varied from 1.3 to 5.7 mg/L (average 4.1 mg/L) on days 9, 11 and 13 postpartum.[2]

A woman took amiodarone 200 mg three times daily for 11 days, then 200 mg twice daily during her pregnancy. She discontinued the drug at the time of delivery and breastfed her infant. The milk amiodarone level was 0.6 mg/L on day 5 and increased to 2.1 mg/L on day 11. The increase between days 5 and 11 could have been due to sampling times (fore- vs hindmilk) or because of an increase in fat content as lactation progressed. Amiodarone was undetectable in milk by day 25.[10]

A postpartum woman was given a single intravenous dose of amiodarone 450 mg for a tachyarrhythmia. Milk samples were collected 3, 4 and 10 days after the dose. At 3 days after the dose, the milk amiodarone concentration was about 185 mcg/L. On day 4, the milk concentration was 233 mcg/L and on day 10, it had fallen to 132 mcg/L. Desethylamiodarone concentrations were not reported. The author estimated that the

amiodarone dose that a fully breastfed infant would receive would be 35 mcg/kg daily, which represents a maximum of 0.18% of the pediatric dosage or 0.6% of the weight-adjusted dose maternal dose.[8]

Infant Levels. A mother took amiodarone 200 mg daily throughout pregnancy and during breastfeeding. Her breastfed infant had serum amiodarone and desethylamiodarone levels of 30 and 320 mcg/L (4.5 and 51% of maternal plasma levels), respectively, at 3 weeks postpartum.[4]

A mother took amiodarone 200 mg daily for the last 5 weeks of pregnancy and for one week after delivery. At 4 weeks postpartum, the breastfed infant's plasma amiodarone and desethylamiodarone levels were 10 and 160 mcg/L, respectively. At 6 weeks postpartum, her breastfed infant's drug and metabolite plasma levels were 10 and 30 mcg/L.[3]

A woman took amiodarone 400 mg daily from week 14 of pregnancy and throughout nursing. Her breastfed infant's serum amiodarone and desethylamiodarone levels were 200 and 50 mcg/L (60% and 14% of maternal levels), respectively, at one day of age and undetectable (<100 and <50 mcg/L, respectively) at 1 and 2 weeks of age.[4]

A woman took amiodarone 800 mg daily for 1 week starting at week 34 of pregnancy, then 400 mg daily for the rest of her pregnancy and during breastfeeding. Her breastfed infant's serum amiodarone level remained constant at 400 mcg/L (about 25% of maternal serum levels) during the first 9 weeks of life, while desethylamiodarone levels slowly decreased from 0.3 (22% of maternal serum levels) to 150 mcg/L (10% of maternal serum levels) during the same time period.[2]

One group reported amiodarone breastmilk levels in 2 patients. The first mother received a total of 7.6 grams of amiodarone over the first 7 days postpartum for ventricular tachycardia and ventricular fibrillation. She collected breastmilk samples between days 10 and 18 postpartum. Back-extrapolation of the sample values indicated an initial amiodarone concentration of 24.8 mg/L that fell with a half-life of 4.4 days. The second patient received a single amiodarone dose of 150 mg intravenously on day 1 postpartum. Breastmilk samples collected on days 4 and 5 postpartum contained amiodarone 0.19 mg/L and 0.17 mg/L, and desethylamiodarone, 0.084 mg/L and 0.085 mg/L, respectively. The authors concluded that breastmilk cessation is probably not necessary after a single dose of 150 mg.[7]

Effects in Breastfed Infants

Several infants who breastfed without apparent harm during maternal amiodarone therapy have been reported.[2-4,10]

One mother took amiodarone during the last 5 weeks of pregnancy and until one week after delivery. She was also taking metoprolol throughout pregnancy and at the time of delivery. Possible signs of hypothyroidism occurred transiently in her breastfed infant at 9 and 24 days of age. This was possibly caused by amiodarone or iodine from amiodarone in breastmilk, although residual amiodarone from transplacental passage is also a possible contributing factor; no abnormalities in cornea or the lungs were found.[4]

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date. However, if amiodarone causes hypothyroidism in the mother, her milk supply could be diminished.

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Substance Identification

Substance Name

Amiodarone

CAS Registry Number

1951-25-3

Drug Class

Breast Feeding

Lactation

Antiarrhythmics