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Oxcarbazepine

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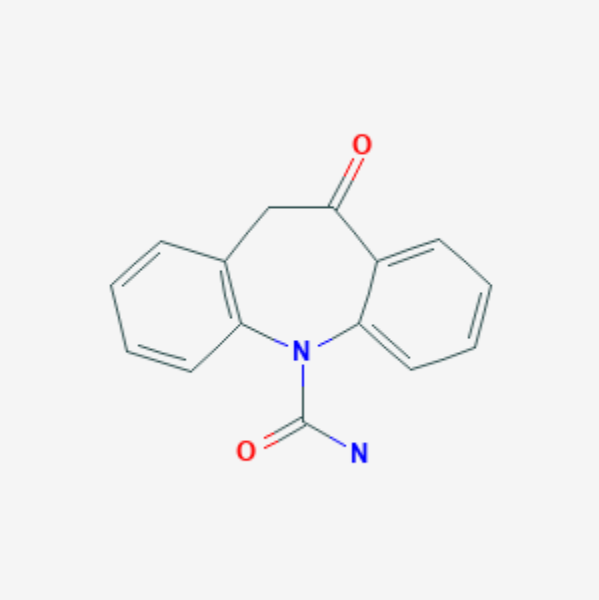
CASRN: 28721-07-5



Drug Levels and Effects

Summary of Use during Lactation

Oxcarbazepine levels in breastmilk are low and it is not expected to cause any adverse effects in breastfed infants, especially if the infant is older than 2 months. Monitor the infant for drowsiness, adequate weight gain, and developmental milestones, especially in younger, exclusively breastfed infants and when using combinations of anticonvulsants.

Drug Levels

In published reports of anticonvulsant use during breastfeeding, most women are taking a combination of anticonvulsants. Some of the other drugs (e.g., phenytoin, carbamazepine) stimulate the metabolism of other anticonvulsants whereas others (e.g., valproic acid) inhibit the metabolism of other anticonvulsants. Therefore,

the relationship of the maternal dosage to the concentration in breastmilk can be quite variable, making calculation of the weight-adjusted percentage of maternal dosage less meaningful than usual.

Maternal Levels. Two women were treated with oxcarbazepine during pregnancy and lactation. Milk levels of the 10-hydroxy-oxcarbazepine metabolite in breastmilk were 50 to 65% of the maternal blood level in one mother during the first week postpartum. In the second mother, milk levels were 70 to 80% of maternal plasma levels during the first 2 months postpartum and 45 to 50% at 2.5 to 4.5 months postpartum. Specific values were not provided in the abstract.[1]

An epileptic woman took oxcarbazepine orally 300 mg 3 times daily during pregnancy and postpartum. Five milk levels of oxcarbazepine and its active metabolite 10-hydroxy-oxcarbazepine taken in the 6 months postpartum were about 50% of maternal blood levels which averaged 380 mcg/L and 5.7 mg/L, respectively. Therefore, milk levels averaged about 190 mcg/L for oxcarbazepine and 2.85 mg/L for 10-hydroxy-oxcarbazepine, although the authors reported that the assay method was not very accurate for breastmilk.[2]

A woman diagnosed with bipolar disorder was taking oxcarbazepine 300 mg every 12 hours (9 mg/kg) by mouth. Milk and blood samples were taken in the morning 11 hours after the previous dose twice at 8 and 23 days postpartum. Oxcarbazepine levels in milk were 0.9 and 1 mg/L, respectively and the levels of the 10-hydroxy metabolite were 5.6 and 10.4 mg/L on the 2 days, respectively. The authors estimated that a fully breastfed infant would receive between 1.5 to 1.7% of the weight-adjusted maternal dosage of oxcarbazepine and its metabolite.[3]

A woman who was receiving oxcarbazepine 150 mg twice daily during pregnancy and postpartum had an oxcarbazepine steady-state peak milk concentration of 7.8 mg/L. The exact time of the milk sample with respect to the dose was not reported.[4]

Infant Levels. Transplacentally acquired plasma levels of oxcarbazepine and 10-hydroxy-oxcarbazepine fell over a 5-day monitoring period in a newborn despite intake via breastmilk. The infant's mother was taking oxcarbazepine orally 300 mg 3 times daily.[2]

A woman diagnosed with bipolar disorder was taking oxcarbazepine 300 mg every 12 hours (9 mg/kg) by mouth. Blood samples were obtained from her breastfed infant (extent not stated) after breastfeeding (exact time not stated) on 2 occasions, at 8 and 23 days of age. The infant had serum concentrations of oxcarbazepine of 0.1 and <0.1 mg/L, respectively and serum concentrations of 10-hydroxy-oxcarbazepine of <0.1 and 0.2 mg/L at the 2 times, respectively. The infants total drug levels were <2.7 and <2.5% of the maternal serum concentrations on the two days.[3]

Two infants whose mothers were taking oxcarbazepine during pregnancy and postpartum breastfeeding (extent not stated) had blood samples at 3 to 4 weeks of age. Their serum 10-hydroxy-oxcarbazepine concentrations were about 5% of their mothers' serum concentrations.[5]

An infant was born to a mother taking oxcarbazepine 150 mg twice daily during pregnancy and postpartum. The infant's serum concentration on postnatal day 6 was 2.6 mg/L, which was about 15% that of the mother's.[4]

In a multicenter study of nursing mother-infant pairs, 6 infants had blood samples taken at about the same time as maternal blood samples. None of the infants had blood levels of oxcarbamazepine above the lower limit of quantification (0.1 mg/L), measured as the active metabolite. The authors estimated the average infant oxcarbazepine serum concentration to be 0.05 mg/L, assuming unquantifiable serum concentrations to be 50% of the lower limit of quantification. Median infant blood levels were 0.3% (range 0.2 to 0.9%) of their mothers' blood levels.[6]

Effects in Breastfed Infants

Two infants were born to mothers who were taking oxcarbazepine (dosage not stated) during pregnancy and postpartum. One infant was breastfed for 1 week and the other for at least 4.5 months (extent not stated). Both infants developed normally.[1]

One infant was breastfed (extent not stated) from day 3 to at least 6 months of age during maternal therapy with oxcarbazepine 300 mg 3 times daily. Examination of the infant at 13 months of age indicated normal development with no signs of mental retardation or neurologic deficit.[2]

An epileptic woman took oxcarbazepine 600 mg twice daily throughout pregnancy and lactation. Her breastfed infant developed normally during the first 4 months of breastfeeding.[7]

A woman took oxcarbazepine monotherapy throughout pregnancy and postpartum for complex partial seizures. She breastfed her infant with some formula supplementation (extent not stated) for 6 months while taking a an oxcarbazepine dosage of 900 mg twice daily. Her infant achieved all developmental milestones for the first 3 years of life.[8]

An infant was breastfed (extent not stated) for 18 weeks by a mother who took oxcarbazepine 300 mg every 12 hours (9 mg/kg) during pregnancy and postpartum. At 23 days of age, liver function tests were normal. No adverse drug effects or developmental delay were seen up to age 5 years.[3]

No adverse effects were reported in 10 newborns who were 4 to 23 days old who were breastfed during maternal intake of levetiracetam 1000 to 3000 mg daily. One mother was also taking tiagabine 30 mg daily, clobazam 45 mg daily and oxcarbazepine 600 mg daily.[9]

An infant was born to a mother taking oxcarbazepine 150 mg twice daily during pregnancy and postpartum. About 12 hours after birth, the infant developed increased excitability, irritability, limb shaking, and increased muscle tone, which occurred every few minutes. The infant was allowed to breastfeed and excitability and muscle tension appeared to be lessened somewhat after feeding, but the increased muscle tone was not improved by day 7.[4]

Effects on Lactation and Breastmilk

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

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Substance Identification

Substance Name

Oxcarbazepine

CAS Registry Number

28721-07-5

Drug Class

Breast Feeding

Lactation

Anticonvulsants