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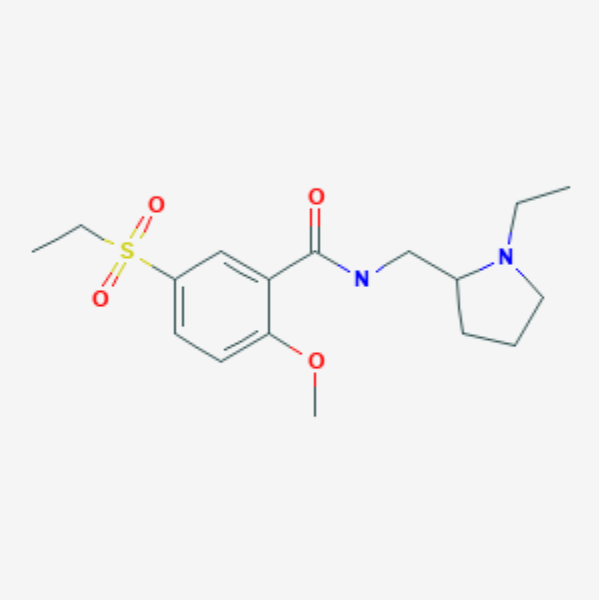
Amisulpride

Revised: March 16, 2020.

CASRN: 53583-79-2



Drug Levels and Effects

Summary of Use during Lactation

Excretion of amisulpride into breastmilk is higher than with other pharmacologically similar drugs. Most information on amisulpride is with continuous oral use as a psychotherapeutic agent. For these uses, an alternate drug may be preferred, especially while nursing a newborn or preterm infant.[1,2] After a single dose for post-operative nausea and vomiting, the manufacturer suggests waiting 48 hours before resuming breastfeeding; however, with a half-life of 4 to 5 hours, a waiting period of 12-24 hours should be adequate to avoid large amounts being excreted into breastmilk.

Drug Levels

Maternal Levels. A nursing mother was taking oral amisulpride 100 mg twice daily at 8:00 am and 12:30 pm, and desvenlafaxine 250 mg daily. Eight breastmilk samples were obtained over a 24-hour period with a breast pump.

The average breastmilk concentration was 1.2 mg/L which equated to an infant dose of 183 mcg/kg daily or 6.1% of the maternal weight-adjusted dosage.[3]

A woman who was 13 months postpartum had been taking amisulpride 400 mg (5 mg/kg) once daily for 9 days. Eight milk samples were obtained over a 24-hour period and consisted of about 50% foremilk and 50% hindmilk. The average breastmilk concentration was 1.6 mg/L which would provide a fully breastfed infant a dose of 534 mcg/kg daily or 10.7% of the maternal weight-adjusted dosage.[4]

A woman began taking amisulpride 100 mg every 12 hours beginning at 34 weeks postpartum and continuing postpartum for psychosis and anxiety. At 4 days postpartum, milk samples were collected before the morning dose and at 4 more times during the 12 hours after the dose. The average concentration of amisulpride in breastmilk was 894 mcg/L. The exclusively breastfed infant would ingest a dose of 0.134 mg/kg daily, corresponding to 4.7% of the maternal weight-adjusted dosage. Because the milk to plasma ratio at the peak time was about 12 times the simultaneous maternal serum concentration and much higher than the predicted ratio of 2.5, the authors suggested that amisulpride is actively secreted into breastmilk.[5]

Infant Levels. A nursing mother had been taking oral amisulpride 100 mg twice daily at 8:00 am and 12:30 pm, and desvenlafaxine 250 mg daily for 12.6 weeks. Her partially breastfed infant was 5 months old. The infant's serum amisulpride concentration 3.1 hours after the mother's daily dose was 4 mcg/L or 3.9% of the maternal serum concentration.[3]

A woman began taking amisulpride 100 mg every 12 hours beginning at 34 weeks postpartum and continuing postpartum for psychosis and anxiety. Her infant was exclusively breastfed. At 4 days postpartum, a blood sample was obtained from the infant at 3.25 hours after the mother's morning dose. The time of the last breastfeeding was not stated. The infant had a serum amisulpride concentration of 10 mcg/L, which was 10.5% of the maternal serum concentration obtained 5 minutes earlier.[5] Some residual effect of transplacental passage cannot be ruled out at 4 days postpartum with the available data.

Effects in Breastfed Infants

A 13-month-old infant was partially breastfed by a mother who was taking amisulpride 400 mg, fluvoxamine 200 mg, and azathioprine 150 mg daily, and was using nicotine chewing gum for smoking cessation. The mother had been taking amisulpride for 9 days; the duration of the other medications was not stated. A pediatric examination found the infant to be developing well.[4]

A woman with long-standing schizophrenia was treated with amisulpride 400 mg and haloperidol 5 mg daily throughout most of her pregnancy and during breastfeeding (extent not stated). Follow-up of the breastfed infant for 13 months by a pediatrician found no adverse effects and normal development of the infant.[6]

Effects on Lactation and Breastmilk

Amisulpride increases serum prolactin and may cause galactorrhea at a higher rate than other psychotropic drugs.[7-12] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

(Antipsychotics) Haloperidol, Olanzapine, Quetiapine, Risperidone

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Substance Identification

Substance Name

Amisulpride

CAS Registry Number

53583-79-2

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents

Dopamine Antagonists