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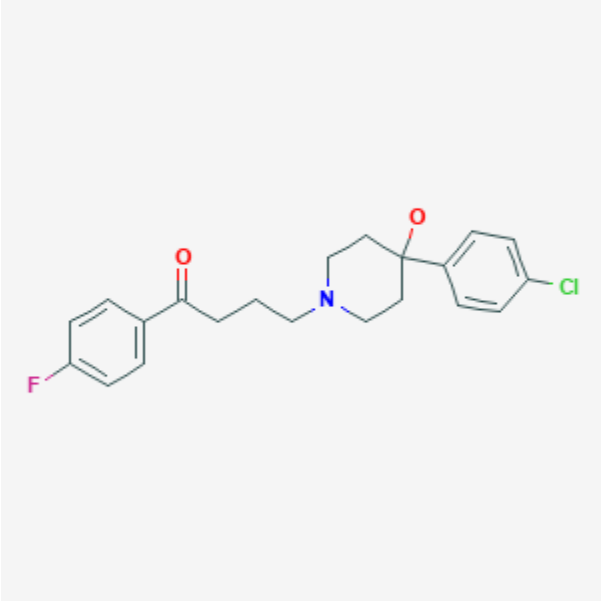
Haloperidol

Revised: June 3, 2019.

CASRN: 52-86-8



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal doses of haloperidol up to 10 mg daily produce low levels in milk and usually do not affect the breastfed infant. Very limited long-term follow-up data indicate no adverse developmental effects when haloperidol is used alone. However, use with other antipsychotic drugs occasionally might negatively affect the infant. Monitor the infant for drowsiness and developmental milestones, especially if other antipsychotics are used concurrently.

Drug Levels

Maternal Levels. In one woman, a milk level of 5 mcg/L was detected 11 hours after a dose during therapy with an average dose of 29.2 mg daily. Another level of 2 mcg/L was measured 9 hours after a 12 mg oral dose. Haloperidol was not detectable in milk 3 days after the last 7 mg dose.[1]

During a regimen of haloperidol 5 mg orally twice daily in one woman, random milk levels were 18 and 23.5 mcg/L. On day 21 of therapy, the mother's milk level was 4 mcg/L.[2]

A woman had been taking haloperidol for 29 days before and after delivery. Although she was not breastfeeding, a breastmilk sample was obtained 12 days postpartum when the dose had been 6 mg orally for 7 days. The milk haloperidol level 3 hours after the last dose was 1.7 mcg/L.[3]

Three patients taking haloperidol 3, 4 and 6 mg daily had random milk levels of 32, 17 and 4.7 mcg/L at unspecified times after a dose, although the latter patient was reportedly nonadherent to the drug regimen.[4][5]

Nine patients who were taking haloperidol had foremilk and/or hindmilk samples collected on 1 to 3 occasions 12 to 15 hours after the previous dose of haloperidol. HPLC assay found that foremilk haloperidol levels ranged from undetectable (<1 mcg/L) to 24.9 mcg/L, with no correlation to the maternal doses of 1 to 40 mg daily. Foremilk haloperidol concentrations correlated better with maternal plasma levels. Hindmilk concentrations were slightly higher than foremilk concentrations when both samples were collected. Measurement of the same samples with an enzyme immunoassay found higher levels, ranging from undetectable (<10 mcg/L) to 988 mcg/L, again correlated better with maternal serum concentrations than maternal dosage. The authors considered the higher values to represent the contribution of undetermined metabolites that were unmeasured by HPLC.[6]

Infant Levels. A nursing mother took haloperidol 5 mg orally twice daily. On day 21 of therapy, the infant's urine contained 1.5 mcg/L of haloperidol.[2]

Four breastfed infants whose mothers were taking haloperidol is doses of 5 to 20 mg daily had serum concentrations measured by enzyme immunoassay. Serum concentrations ranged from 0.8 to 2.1 mcg/L. Neither the extent of nursing, the exact age at the time of sample collection, nor the time of sampling were stated.[6]

Effects in Breastfed Infants

In one breast-fed infant, there were no sedative effects and the baby fed well during maternal intake of 5 mg orally twice daily. The mother took haloperidol during six weeks of breast feeding and at 6 and 12 months of age, the baby had achieved all milestones of growth and development.[2]

One infant was breastfed for 5 weeks beginning at 2 weeks of age during maternal haloperidol (dose not stated) and imipramine (150 mg daily) therapy. The infant showed normal development when tested once between 1 and 4 months and once between 12 and 18 months of age.[7]

In a small prospective study on the long-term effects of antipsychotics in breastfed infants, a decline in developmental scores was found at 12 to 18 months of age in 2 of the 4 the infants of mothers taking both chlorpromazine and haloperidol. The other 2 infants and all infants exposed to either drug alone developed normally.[6]

One woman with schizophrenia took haloperidol and trihexyphenidyl during 3 pregnancies and postpartum. Haloperidol doses were 7.5 to 10 mg daily in the first 2 pregnancies and 15 mg daily in the third. She breastfed (extent not stated) all 3 children for 6 to 8 months using the same doses. Development was age-appropriate in all children aged 16 months at 8 years of age at the time of assessment.[8]

Two women, one with bipolar disorder and the other with long-standing schizophrenia, were treated with haloperidol 5 mg daily during pregnancy and breastfeeding (extent not stated). One mother also received olanzapine 10 mg daily and the other received amisulpride 400 mg daily. Follow-up of the breastfed infants for 11 to 13 months found no adverse effects and normal development of the infants.[9]

A woman diagnosed with schizophrenia was taking risperidone 1.5 mg daily during late pregnancy and postpartum while nursing (extent not stated) her full-term infant. At 2 weeks postpartum, haloperidol 0.8 mg

daily was added because of a recurrence of symptoms. At these dosages, no adverse effects were seen in the infant. However, because of recurring symptoms, the dosage of haloperidol was increased to 1.5 mg daily. Three days later, the infant had excessive sedation, poor feeding, and slowing in motor movements. Pediatric assessment found no medical reason for these effects. Breastfeeding was discontinued and the infant's symptoms resolved completely in 5 days. The infant's symptoms were probably caused by the drug combination.[10]

Effects on Lactation and Breastmilk

Galactorrhea has been reported with haloperidol.[11] Hyperprolactinemia appears to be the cause of the galactorrhea.[11][12][13][14][15][16] The hyperprolactinemia is caused by the drug's dopamine-blocking action in the tuberoinfundibular pathway.[17] The maternal prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Olanzapine, Risperidone

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Substance Identification

Substance Name

Haloperidol

CAS Registry Number

52-86-8

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents

Butyrophenones