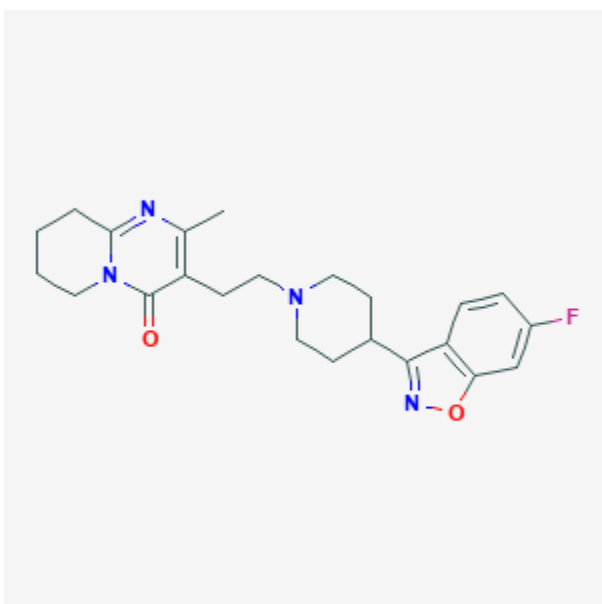




Risperidone

Revised: February 17, 2020.

CASRN: 106266-06-2



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal risperidone doses of up to 6 mg daily produce low levels in milk. However, use with other antipsychotic drugs occasionally might negatively affect the infant. Because there is little published experience with risperidone during breastfeeding and little long-term follow-up data, other agents may be preferred, especially while nursing a newborn or preterm infant. Systematic reviews of second-generation antipsychotics concluded that risperidone seemed to be a second-line agent during breastfeeding because of the limited data available and higher excretion into milk relative to other agents.[1][2] Monitor the infant for drowsiness and developmental milestones, especially if other antipsychotics are used concurrently.

Drug Levels

Maternal Levels. One mother taking risperidone 6 mg daily had milk and serum levels of risperidone and its active metabolite, 9-hydroxyrisperidone, measured over 24 hours. Results indicated that an exclusively breastfed infant would receive 0.84% of the maternal weight-adjusted dosage of risperidone and another 3.46% as 9-hydroxyrisperidone for a total of 4.3% of the maternal weight-adjusted dosage.[3]

Two breastfeeding women taking 2 mg twice daily and 1.5 mg daily in 2 divided doses, respectively, and another with risperidone-induced galactorrhoea taking 3 mg once daily were studied. Both risperidone and 9-hydroxyrisperidone were measured in milk. Milk levels of the drugs were rather flat during the 12 to 24 hours after the dose. The mean dose that an exclusively breastfed infant would receive was calculated to be 3.3% (range 2.2 to 4.7%) of the maternal weight-adjusted dosage.[4]

A woman who was 1 week postpartum was started on oral risperidone 2 mg daily and increased to 3 mg once daily. On day 6 of therapy (dosage 2 mg daily) average milk levels at 3 hours after a dose were risperidone 2.5 mcg/L and 9-hydroxyrisperidone 10 mcg/L. On day 10 (dosage 2 mg daily) at 15 hours after a dose 9-hydroxyrisperidone averaged 1.2 mcg/L and risperidone was undetectable. On day 20 of therapy (dosage 3 mg daily) average milk levels at 16 hours after a dose were risperidone 0.1 mcg/L and 9-hydroxyrisperidone 2.5 mcg/L.[5]

A woman took risperidone during pregnancy and breastfeeding. At 3 months postpartum, she provided 6 foremilk samples over a 24-hour period after her daily dose while she was taking a dose of 1 mg daily. Milk was analyzed for risperidone and 9-hydroxyrisperidone by HPLC. Risperidone could not be detected in milk (assay limit not specified). Breastmilk 9-hydroxyrisperidone was about 3 mcg/L at 1 and 24 hours later; its concentration was about 4 mcg/L at 2, 4, 8, 18 and 23 hours after the dose. The authors estimated that a fully breastfed infant would receive 4.7% of the maternal weight-adjusted dosage as 9-hydroxyrisperidone.[6]

Infant Levels. In 2 breastfed infants (6 weeks and 3.3 months old) whose mothers were taking 2 mg twice daily and 1.5 mg daily in 2 divided doses, respectively, risperidone and 9-hydroxyrisperidone were both undetectable (<1 mcg/L) in the serums of the infants.[4]

An infant was breastfed 6 times daily during maternal therapy with risperidone 2 mg once daily. Fifteen hours after the mother's last dose, the infant's plasma levels of risperidone was undetectable and 9-hydroxyrisperidone was 0.1 mcg/L.[5]

An infant was exclusively breastfed on demand during maternal therapy with risperidone 1 mg daily. At 3 months of age, risperidone was undetectable in the infant's serum 6 hours after a maternal dose.[6]

Effects in Breastfed Infants

One woman took risperidone 4 mg daily during breastfeeding. Her infant showed no developmental abnormalities on examinations up to 9 months of age. Another mother took risperidone 6 mg daily during breastfeeding. Her infant showed no developmental abnormalities on examinations up to 12 months of age.[7]

Two women taking risperidone 4 mg and 1.5 mg daily breastfed their infants of 3.3 months and 6 weeks of age, respectively, were achieving normal developmental milestones and had no adverse effects reported.[4]

A 1 week postpartum woman was started on risperidone 2 mg daily and increased after 10 days to a dosage of 3 mg daily. She breastfed her infant 6 times daily. The infant was observed for 5 weeks of inpatient therapy and judged normal by a pediatric neurologist. No sedation or other adverse effects were observed in the infant. After 3 months of treatment with risperidone, the mother and infant were judged to be well.[5]

An infant had been exclusively breastfed for 3 months during maternal therapy with risperidone 1 mg daily. A pediatric examination found the infant to have no neurological or physical abnormalities, and appeared to interact appropriately.[6]

In a telephone follow-up study, 124 mothers who took a benzodiazepine while nursing reported whether their infants had any signs of sedation. One mother who was taking 0.75 mg of risperidone daily, flurazepam 15 mg daily, clonazepam 0.25 mg twice daily, and 1 mg of bupropion daily reported sedation in her breastfed infant.[8]

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.[9]

Effects on Lactation and Breastmilk

Risperidone has caused elevated prolactin serum levels, gynecomastia, and galactorrhea in patients taking the drug.[10][11][12][13][14][15][16][17] In one case, euprolactinemic gynecomastia and galactorrhea occurred in a 19-year-old man who was also taking fluvoxamine.[18] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Haloperidol, Olanzapine, Quetiapine

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Substance Identification

Substance Name

Risperidone

CAS Registry Number

106266-06-2

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents