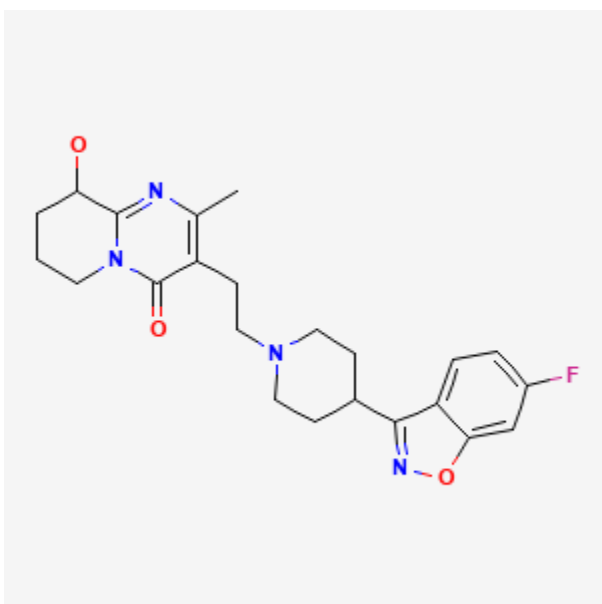




Paliperidone

Revised: August 15, 2023.

CASRN: 144598-75-4



Drug Levels and Effects

Summary of Use during Lactation

Although no data are available for the use of paliperidone during breastfeeding, it is the active metabolite of risperidone. Risperidone data indicate that the concentrations of paliperidone (9-hydroxyrisperidone) in breastmilk are low, and amounts ingested by the infant are small. A safety scoring system finds paliperidone possible to use cautiously during breastfeeding,[1] although others do not recommend it.[2] Because there is no published experience with paliperidone during breastfeeding and little long-term follow-up data, other agents may be preferred, especially while nursing a newborn or preterm infant. Because paliperidone is available only as long-acting products, timing of nursing with respect to doses would not be useful. Long-acting injectable formulations may continue to deliver small amounts to breastmilk for many months. Monitor breastfed infants for drowsiness, adequate growth and weight gain, jitteriness, tremors, and abnormal movements.

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Paliperidone is 9-hydroxyrisperidone, the active metabolite of risperidone. No studies have measured paliperidone in breastmilk after administration of paliperidone. However, 9-hydroxyrisperidone has been measured in milk and plasma after administration of risperidone.

Maternal Levels. The manufacturer reports that the average adult plasma concentration of paliperidone after the maximum dose of 12 mg daily is about 37 mcg/L.[3] Using the average milk-to-plasma ratio of 9-hydroxyrisperidone of 0.3 from 3 reports of risperidone use during breastfeeding,[4-6] the average milk concentration would be expected to be about 11 mcg/L or a dose of 1.7 mcg/kg daily. An exclusively breastfed infant would receive an average of less than 1% of the maternal weight-adjusted dosage with this maternal dosage.

Infant Levels. In 2 breastfed infants (6 weeks and 3.3 months old) whose mothers were taking 2 mg of risperidone 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.[5]

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.[6]

Effects in Breastfed Infants

No published information on paliperidone was found as of the revision date. However, limited data from the use of its parent drug, risperidone, during nursing indicate no short- or long-term adverse effects on the infant.[5-7]

Patients enlisted in the National Pregnancy Registry for Atypical Antipsychotics who were taking a second-generation antipsychotic drug while breastfeeding (n = 576) were compared to control breastfeeding patients who were not treated with a second-generation antipsychotic (n = 818). Of the patients who were taking a second-generation antipsychotic drug, 60.4% were on more than one psychotropic. A review of the pediatric medical records, no adverse effects were noted among infants exposed or not exposed to second-generation antipsychotic monotherapy or to polytherapy.[8] The number of women taking paliperidone was not reported.

Effects on Lactation and Breastmilk

Paliperidone has caused elevated prolactin serum levels, gynecomastia, and galactorrhea in patients taking the drug.[9-16] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Patients enlisted in the National Pregnancy Registry for Atypical Antipsychotics who were taking a second-generation antipsychotic drug while breastfeeding (n = 576) were compared to control breastfeeding patients who had primarily diagnoses of major depressive disorder and anxiety disorders, most often treated with SSRI or SNRI antidepressants, but not with a second-generation antipsychotic (n = 818). Among women on a second-generation antipsychotic, 60.4% were on more than one psychotropic compared with 24.4% among women in the control group. Of the women on a second-generation antipsychotic, 59.3% reported "ever breastfeeding" compared to 88.2% of women in the control group. At 3 months postpartum, 23% of women on a second-generation antipsychotic were exclusively breastfeeding compared to 47% of women in the control group.[8] The number of women taking paliperidone was not reported.

Alternate Drugs to Consider

Haloperidol, Olanzapine, Quetiapine, Risperidone

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Substance Identification

Substance Name

Paliperidone

CAS Registry Number

144598-75-4

Drug Class

Breast Feeding

Lactation

Milk, Human

Antipsychotic Agents