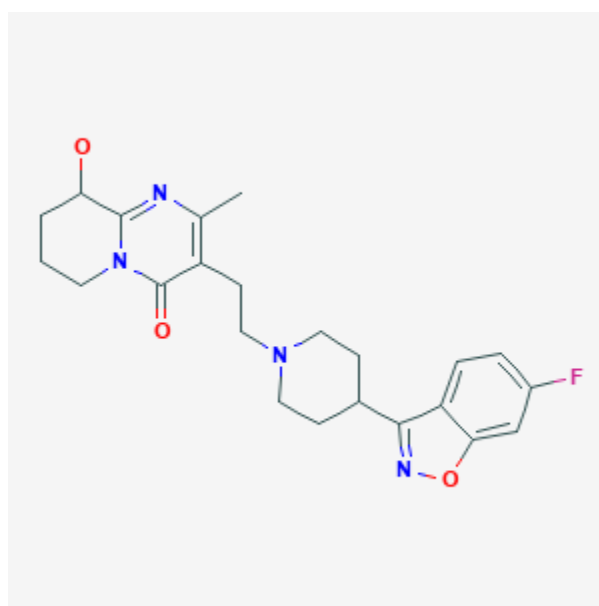




Paliperidone

Revised: October 31, 2018.

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. 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 a sustained-release product, timing of nursing with respect to doses would not be useful.

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.[1] Using the average milk-to-plasma ratio of 9-hydroxyrisperidone of 0.3 from 3 reports of risperidone use during breastfeeding,[2][3][4] 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.[3]

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.[4]

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.[3][4][5]

Effects on Lactation and Breastmilk

Paliperidone has caused elevated prolactin serum levels, gynecomastia, and galactorrhea in patients taking the drug.[6][7][8][9][10][11] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Haloperidol, Olanzapine

References

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Substance Identification

Substance Name

Paliperidone

CAS Registry Number

144598-75-4

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents