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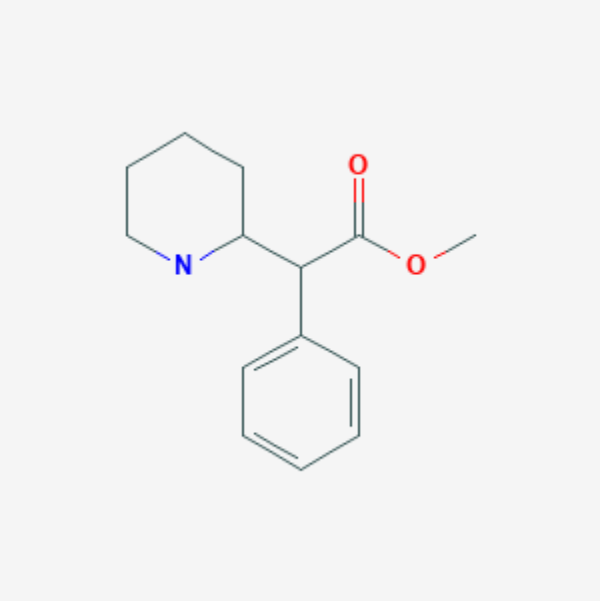
NLM Citation: Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Methylphenidate. [Updated 2019 Oct 23].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Methylphenidate

Revised: October 23, 2019.

CASRN: 113-45-1



Drug Levels and Effects

Summary of Use during Lactation

In dosages prescribed for medical indications, limited evidence indicates that methylphenidate levels in milk are very low and not detectable in infant serum. The effects of methylphenidate in milk on the neurological development of the infant have not been well studied. If methylphenidate is required by the mother, it is not a reason to discontinue breastfeeding.[1] It is possible that large dosages of methylphenidate might interfere with milk production, especially in women whose lactation is not well established.

Drug Levels

Maternal Levels. Three mothers were taking methylphenidate in an average dosage of 52 mg daily (range 35 to 80 mg daily) for attention deficit hyperactivity disorder. The average milk level was 19 mcg/L which resulted in an infant dosage of 2.9 mcg/kg daily or 0.7% of the maternal weight-adjusted dosage.[2]

The same authors reported a nursing mother who was taking methylphenidate, but it is unclear if this patient is one of those reported above. The mother was taking 40 mg twice daily, 5 days/week for 5.5 weeks prior to testing, but for 7 consecutive days immediately before collecting blood and milk samples after a morning dose of 40 mg. The average milk level of methylphenidate over the 24 hours after the dose was 15.4 mcg/L. The infant was calculated to receive 2.3 mcg/kg daily which was 0.2% of the maternal weight-adjusted dosage.[3]

A woman who was 11 months postpartum was taking oral immediate-release methylphenidate 5 mg in the morning and 10 mg at noon. The drug was undetectable (<0.3 mcg/L) before the morning dose and 21 hours after the noon dose. Three other levels ranged from1.7 to 3.8 mcg/L. The authors estimated that a fully breastfed infant would receive a dose of 0.38 mcg/kg daily or 0.16% of the maternal weight-adjusted dosage.[4]

A woman was taking 72 mg daily of slow-release methylphenidate. The drug was undetectable (assay limit not stated) in breastmilk at 6 to 12 months postpartum.[5]

A partially nursing mother was taking extended-release methylphenidate (Concerta) 36 mg daily and duloxetine 90 mg daily for ADHD, generalized anxiety disorder, borderline personality disorder, and depression. On day 29, a milk sample was taken 6.5 hours after her doses. The methylphenidate concentration in milk was 7.9 mcg/L with an estimated relative infant dosage of 0.2%, assuming milk intake of 150 mL/kg daily.[6]

Infant Levels. Methylphenidate blood levels were measured in 2 breastfed infants. These were 2 of 3 infants whose mothers were taking an average of 52 mg daily of methylphenidate. The drug was undetectable (<1 mcg/L) in the infants' blood; however, the corresponding maternal dosages and times of blood collection were not stated in the abstract.[2]

A 6.4-month-old partially breastfed infant had been breastfed for 5.5 weeks by a mother taking methylphenidate 40 mg twice daily. The drug was undetectable (<1 mcg/L) in the infant's plasma 5.3 hours after the mother's dose and having been breastfed 4 times since the dose.[3] This patient might have been one of those in the report above by the same authors.

An infant was born to a mother with attention deficit-hyperactivity disorder who took a tapering dose of methylphenidate before and during pregnancy. The drug was stopped 10 days prior to delivery, but restarted after 5 weeks postpartum. Methylphenidate was undetectable (assay limit not stated) in the infant's blood between 6 and 2 months of age when the mother was taking a dose of 72 mg of slow-release methylphenidate daily. The extent of breastfeeding was not stated.[5]

Effects in Breastfed Infants

Seven of 8 infants, whose mothers were taking either dextroamphetamine (average dosage 25 mg daily) or methylphenidate (average dosage 52 mg daily) were clinically evaluated. The infants had no drug-related adverse reactions and were developing normally for their ages which averaged 4.4 months.[2]

One 6.4-month-old infant was mostly breastfed by a mother who had been taking methylphenidate 40 mg twice daily 5 days/week for 5.5 weeks. The mother reported that the infant was sleeping, eating and gaining weight normally.[3] This patient might have been one of those in the report above by the same authors.

An infant was being breastfed (extent not stated) by a mother who began taking sertraline 50 mg daily and methylphenidate after 5 weeks postpartum. Dosage was started at 10 mg daily with an immediate-release product and gradually increased to 72 mg daily of an extended-release product. At 14 weeks of age, the infant was developing normally no feeding difficulties. Examinations at 6 months and 1 year of age found no developmental problems in the child.[5]

A nursing mother was taking extended-release methylphenidate (Concerta) 36 mg daily and duloxetine 90 mg daily for ADHD, generalized anxiety disorder, borderline personality disorder, and depression. She partially

(amount not stated) breastfed her infant for about 1 month. At 6 months of age, the infant's development was considered to be normal, except for recurrent pneumonia caused by congenital pulmonary airway malformation.[6]

Effects on Lactation and Breastmilk

Methylphenidate reduces serum prolactin,[7] but no studies have been located as of the revision date on the effect of methylphenidate on milk production. The maternal prolactin level in a mother with established lactation may not affect her ability to breastfeed.

A 15-year-old girl had been receiving methylphenidate 54 mg daily in an osmotic release tablet (OROS) for 2 years. Sertraline was started for depression at 50 mg daily and increased to 100 mg daily along with haloperidol 0.5 mg daily. After 12 weeks of therapy, inattentativeness at school and headaches prompted a change from the OROS product to a modified-release methylphenidate product (brand not specified) at 30 mg daily, then increasing to 50 mg daily. Three days after the increase in dosage, the girl had spontaneous milk flow from both breasts and subsequently had an elevated serum prolactin of 67.7 mcg/L. Methylphenidate and haloperidol were discontinued, but sertraline was continued. One week later, galactorrhea resolved completely. Fifteen days after drug discontinuation, the girl's prolactin level was in the normal range at 19.4 mcg/L.[8]

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Substance Identification

Substance Name

Methylphenidate

CAS Registry Number

113-45-1

Drug Class

Breast Feeding

Lactation

Adrenergic Agents

Central Nervous System Stimulants

Dopamine Agents

Sympathomimetics