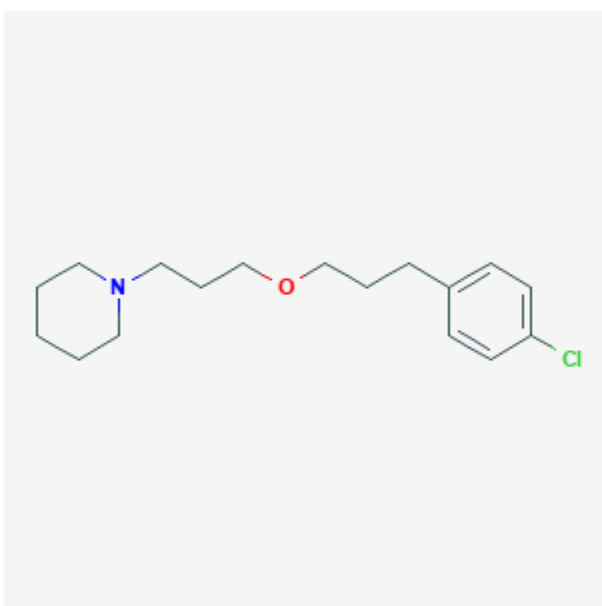




## Pitolisant

Revised: January 15, 2023.

CASRN: 362665-56-3



## Drug Levels and Effects

### Summary of Use during Lactation

No information is available on the clinical use of pitolisant during breastfeeding. However, amounts in breastmilk appear to be low and would not be expected to cause any adverse effects in breastfed infants. If pitolisant is required by the mother, it is not a reason to discontinue breastfeeding. Until more safety data are available, pitolisant should be used with careful infant monitoring during breastfeeding.

### Drug Levels

*Maternal Levels.* The manufacturer reports an open-label study in 8 healthy lactating women who were 11 to 96 weeks post-partum. Breastmilk samples were collected over 24 hours after a single dose of 35.6 mg of pitolisant.

**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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Pitolisant had a mean peak milk concentration of 47.5 mcg/L with about 50% of the amount of pitolisant measured in breastmilk found during the first 4 hours after the maternal dose. The mean infant dosage of pitolisant was calculated to be 0.009 mg daily, which represented a mean of 0.56% of the maternal weight-adjusted dosage.

*Infant Levels.* Relevant published information was not found as of the revision date.

### **Effects in Breastfed Infants**

Relevant published information was not found as of the revision date.

### **Effects on Lactation and Breastmilk**

Relevant published information was not found as of the revision date.

### **Alternate Drugs to Consider**

(Narcolepsy) Amphetamine, Armodafinil, Dextroamphetamine, Lisdexamfetamine, Methylphenidate, Modafinil

## **Substance Identification**

### **Substance Name**

Pitolisant

### **CAS Registry Number**

362665-56-3

### **Drug Class**

Breast Feeding

Lactation

Milk, Human

Histamine H3 Antagonists

Wakefulness-Promoting Agents