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#### **Itraconazole**

Revised: September 19, 2022.

CASRN: 84625-61-6

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# **Drug Levels and Effects**

### **Summary of Use during Lactation**

No information is available on the clinical use of itraconazole during breastfeeding. However, limited data indicate that maternal itraconazole produces levels in milk that are less than the 5 mg/kg daily doses that have been recommended to treat infants. Until more data become available, an alternate drug may be preferred, especially while nursing a newborn or preterm infant. If itraconazole is used during breastfeeding, monitoring of the infant's liver enzymes should be considered, especially with long courses of therapy.

**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**

Maternal Levels. An unpublished study reported 2 healthy volunteers who each took 2 oral doses of itraconazole 200 mg 12 hours apart. Milk samples were obtained with a breast pump at 4, 24, and 48 hours after the second dose. The average milk concentrations of itraconazole were 70.2, 27.7, and 16.2 mcg/L, respectively. At 72 hours, the milk level was 20.1 mcg/L in one woman and not detectable (<5 mcg/L) in the other. However, steady-state was probably not attained at the time of sampling, and metabolites including the active hydroxyitraconazole were not measured.[1]

Using data reported in the literature, including the above source, researchers estimated that fully breastfed infants between 3 and 12 months of age would receive 1.48% of the mother's weight-adjusted dosage of itraconazole and attain a plasma concentration of 0.77% of the mother's plasma concentration.[2]

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**

Fluconazole

#### References

- 1. Briggs GG, Freeman RK, Towers CV, et al. Drugs in pregnancy and lactation, 11th ed. Baltimore. Williams & Wilkins. 2017.
- 2. McNamara PJ, Abbassi M. Neonatal exposure to drugs in breast milk. Pharm Res. 2004;21:555–66. PubMed PMID: 15139511.

#### **Substance Identification**

#### Substance Name

Itraconazole

### **CAS Registry Number**

84625-61-6

### **Drug Class**

**Breast Feeding** 

Lactation

Milk, Human

**Antifungal Agents**