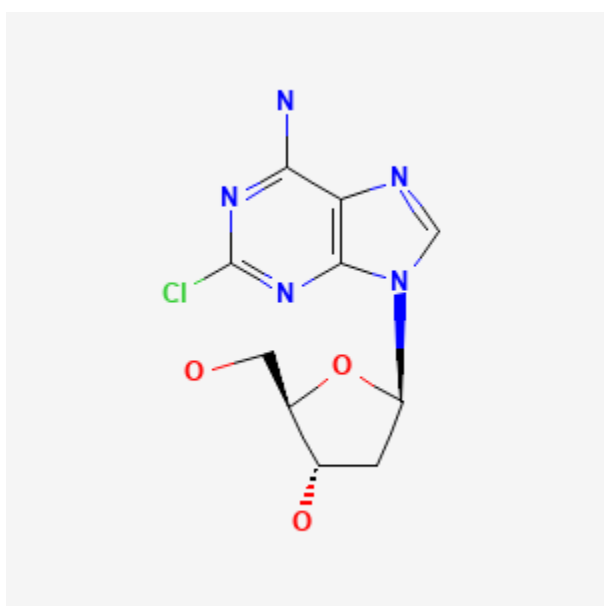




Cladribine

Revised: September 15, 2023.

CASRN: 4291-63-8



Drug Levels and Effects

Summary of Use during Lactation

The amount of cladribine in milk is low with oral doses of 10 to 20 mg daily used in multiple sclerosis. Data in one patient indicates that the drug is rapidly eliminated over 24 hours and undetectable at 48 hours after a dose. Manufacturers recommend a 7-day (Europe) or 10-day (US) abstinence period. Chemotherapy may adversely affect the normal microbiome and chemical makeup of breastmilk.[1] Women who receive chemotherapy during pregnancy are more likely to have difficulty nursing their infant.[2]

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. A woman with multiple sclerosis who was 4 months postpartum began cladribine. In her second course of therapy, 5 weeks after the first course, she received 20 mg cladribine once daily by mouth on days 1 to 3 and 10 mg on days 4 and 5. On day 3, the patient collected samples at 0, 1, 2, 4, 6, 8, 12, and 24 hours after a 20 mg dose. The highest milk level was 281 mcg/L at 1 hour after the dose. Levels declined rapidly over 12 to 24 hours, to undetectable (<1.5 mcg/L) levels at 48 hours and beyond. The average milk level was 44 mcg/L over the 24 hour period. The authors calculated that a fully breastfed infant would receive a dose of 6.6 mcg/kg daily, which corresponds to a weight-adjusted dose of 3.1% of the maternal dose.[3] A further analysis of two patients taking cladribine for multiple sclerosis found relative infant dosages of 2.99% with a 10 mg daily dosage and 4.73% with a 20 mg daily dosage. Peak milk concentrations were seen at 1 and 2 hours after the dose, respectively.[4]

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

(Multiple Sclerosis) [Glatiramer](#), [Immune Globulin](#), [Interferon Beta](#), [Methylprednisolone](#)

References

1. Urbaniak C, McMillan A, Angelini M, et al. Effect of chemotherapy on the microbiota and metabolome of human milk, a case report. *Microbiome* 2014;2:24. PubMed PMID: 25061513.
2. Stopenski S, Aslam A, Zhang X, Cardonick E. After chemotherapy treatment for maternal cancer during pregnancy, is breastfeeding possible? *Breastfeed Med* 2017;12:91-7. PubMed PMID: 28170295.
3. Datta P, Ciplea AI, Rewers-Felkins K, et al. Cladribine transfer into human milk: A case report. *Mult Scler* 2021;27:799-801. PubMed PMID: 32507055.
4. Datta P, Hale TW, Thiel S, et al. Low transfer of cladribine into human milk. *Mult Scler* 2023;29:1346-7. PubMed PMID: 37392023.

Substance Identification

Substance Name

Cladribine

CAS Registry Number

4291-63-8

Drug Class

Breast Feeding

Lactation

Milk, Human

Antineoplastic Agents

Immunosuppressive Agents