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Dimethyl Fumarate

Revised: September 19, 2022.

CASRN: 624-49-7

Drug Levels and Effects

Summary of Use during Lactation

No information is available on the clinical use of dimethyl fumarate during breastfeeding. However, amounts of the active metabolite of dimethyl fumarate, monomethyl fumarate, in breastmilk appear to be low and would not be expected to cause any adverse effects in breastfed infants. Before any data were available, some authors recommend avoiding breastfeeding during dimethyl fumarate therapy,[1,2] others and the US manufacturer did not.[3] Breastfed infants should be monitored for adequate weight gain, and developmental milestones, especially in younger, exclusively breastfed infants. Some authors also recommend monitoring breastfed infants for flushing, vomiting and diarrhea.[3,4]

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

Dimethyl fumarate is not found in the plasma because it is rapidly converted to the active drug, monomethyl fumarate, which has a half-life of about 1 hour.

Maternal Levels. Two nursing mothers with relapsing-remitting multiple sclerosis began oral dimethyl fumarate 240 mg twice daily after discontinuing breastfeeding. They continued pumping milk and on day 8 of therapy, they each provided milk samples at 1, 2, 4, 8 and 12 hours after a dose. Peak monomethyl fumarate milk levels were 3.7 mcg/L in one mother and 11.2 mcg/L in the other and occurred at about 2 hours after the dose. Average milk levels were 2.7 mcg/L and 7.5 mcg/L, respectively. These values indicate that the infants would receive daily dosages of about 0.8 mcg/kg and 1.13 mcg/kg, respectively, or weight-adjusted relative infant dosages of 0.007% and 0.019% of the maternal dosage.[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

References

- 1. Bove R, Alwan S, Friedman JM, et al. Management of multiple sclerosis during pregnancy and the reproductive years: A systematic review. Obstet Gynecol. 2014;124:1157–68. PubMed PMID: 25415167.
- 2. Thöne J, Thiel S, Gold R, et al. Treatment of multiple sclerosis during pregnancy safety considerations. Expert Opin Drug Saf. 2017;16:523–34. PubMed PMID: 28333552.
- 3. Almas S, Vance J, Baker T, et al. Management of multiple sclerosis in the breastfeeding mother. Mult Scler Int. 2016;2016:6527458. PubMed PMID: 26966579.
- 4. Ciplea AI, Datta P, Rewers-Felkins K, et al. Dimethyl fumarate transfer into human milk. Ther Adv Neurol Disord. 2020;13 doi: 10.1177/1756286420968414.

Substance Identification

Substance Name

Dimethyl Fumarate

CAS Registry Number

624-49-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Dimethyl Fumarate 3

Dermatologic Agents

Immunosuppressive Agents

Radiation-Sensitizing Agents