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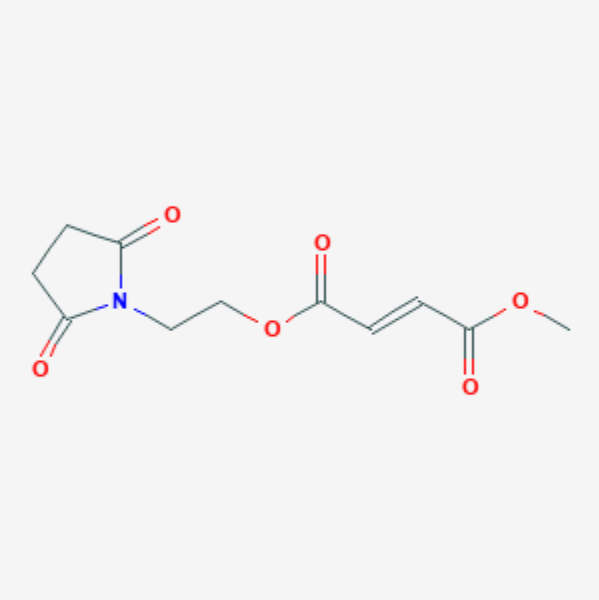
Diroximel Fumarate

Revised: May 15, 2024.

CASRN: 1577222-14-0



Drug Levels and Effects

Summary of Use during Lactation

No information is available on the clinical use of diroximel fumarate during breastfeeding. However, amounts of the active metabolite of diroximel fumarate, monomethyl fumarate, in breastmilk appear to be low and would not be expected to cause any adverse effects in breastfed infants. Based on clinical data in over 20 infants exposed to dimethyl fumarate in breastmilk, diroximel fumarate is acceptable to use during breastfeeding, at least after one month of age.[1] 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.[2,3]

Drug Levels

Diroximel 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 the closely related drug dimethyl fumarate 240 mg orally 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.[3]

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

Effects in Breastfed Infants

Twenty-six women taking dimethyl fumarate for relapsing-remitting multiple sclerosis were followed during 29 pregnancies from 2015 to 2020. Dimethyl fumarate was administered through week 24 of pregnancy and resumed 1 month after delivery. Twenty-two of 26 mothers breastfed (extent not stated) for 4 to 7 months. Infants were monitored up to the third year of life for infections and developmental disorders. All children were the 70th and 95th percentile for height and weight. The authors concluded that continuing dimethyl fumarate while breastfeeding is safe,[1] although infants were not exposed during the first month of life.

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. Borriello G, Ianniello A. Efficacy, safety and tolerability of dimethylfumarate during pregnancy and breastfeeding. Mult Scler Relat Disord 2022;67:103949. doi:10.1016/j.msard.2022.103951
2. 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.
3. Ciplea AI, Datta P, Rewers-Felkins K, et al. Dimethyl fumarate transfer into human milk. Ther Adv Neurol Disord 2020;13:1756286420968414. PubMed PMID: 33193814.

Substance Identification

Substance Name

Diroximel Fumarate

CAS Registry Number

1577222-14-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Dermatologic Agents

Immunosuppressive Agents

Radiation-Sensitizing Agents