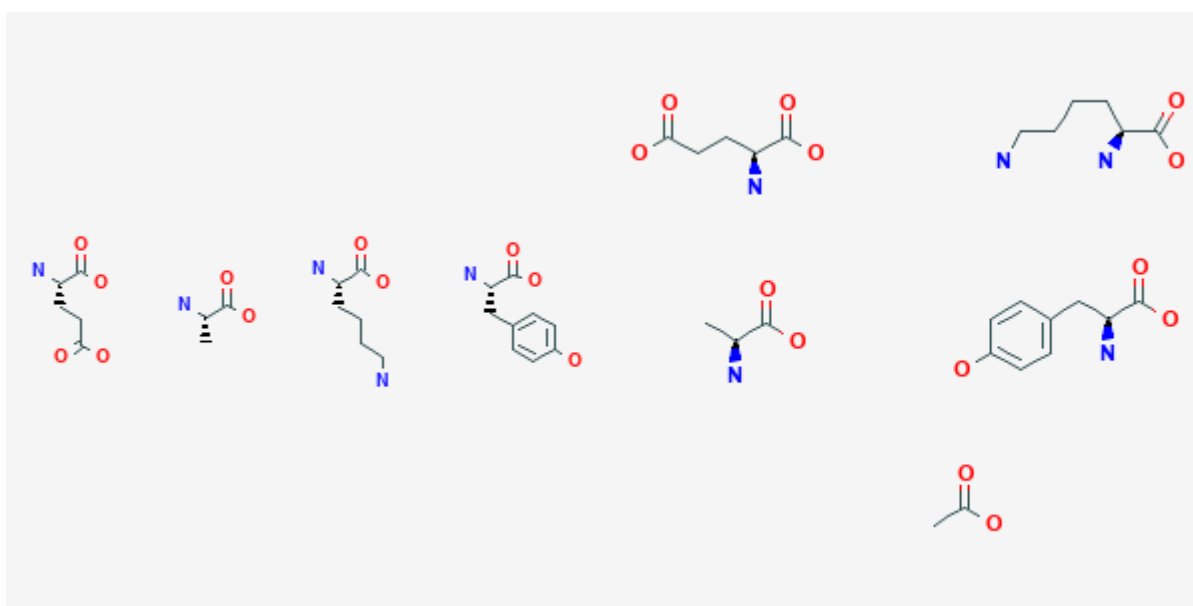




## Glatiramer

Revised: March 16, 2020.

CASRN: 28704-27-0



## Drug Levels and Effects

### Summary of Use during Lactation

Glatiramer is the active portion of the drug, glatiramer acetate. No information is available on the excretion of glatiramer acetate into breastmilk. However, data from the manufacturer indicates that after subcutaneous injection, glatiramer undergoes rapid degradation to amino acids and shorter peptides and that it cannot be detected in the plasma, urine or feces.[1] Furthermore, any glatiramer that did reach the breastmilk would probably be destroyed in the infant's gastrointestinal tract and not absorbed, except perhaps in neonates. Limited information indicates that maternal use of glatiramer acetate does not cause any adverse effects in breastfed infants. Glatiramer acetate is generally considered safe by most experts and appears to be one of the preferred disease-modifying agents for treating multiple sclerosis during breastfeeding.[2-5]

## Drug Levels

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

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

## Effects in Breastfed Infants

Nine mothers received glatiramer acetate (dosage not stated) during pregnancy and postpartum for multiple sclerosis and breastfed their infants for an average of 3.6 months (range 1 to 12 months). No infections, signs of inadequate digestion or other important ill effects were reported in their breastfed infants during the neonatal period. Follow-up of the infants at 1 year or longer found no neurological or developmental deficits in the infants except for one otherwise normal infant with delayed language development who had been breastfed for 3 months.[6]

Three mothers received glatiramer acetate (dosage not stated) for multiple sclerosis during pregnancy and postpartum. All of their infants were exclusively breastfed for 6 months and no noticeable problems were reported in any of them.[7]

In data collected from 4 countries, 41 women received glatiramer acetate and 17 women received interferon during pregnancy and postpartum for treatment of multiple sclerosis. Of these, 63% breastfed (extent not stated) their infants for a mean of 8.8 months. No mention was made of adverse reactions in breastfed infants.[8]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

Immune Globulin, Interferon Beta, Methylprednisolone

## References

1. Ziemssen T, Neuhaus O, Hohlfeld R. Risk-benefit assessment of glatiramer acetate in multiple sclerosis. *Drug Saf.* 2001;24:979–90. PubMed PMID: 11735654.
2. 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.
3. Fragoso YD. Glatiramer acetate to treat multiple sclerosis during pregnancy and lactation: A safety evaluation. *Expert Opin Drug Saf.* 2014;13:1743–8. PubMed PMID: 25176273.
4. Thone 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.
5. Ciplea AI, Stahl A, Thiel S, et al. Interferon-beta/glatiramer acetate treatment during lactation in women with multiple sclerosis. *Mult Scler J.* 2018;24:552–3 Abstract P1004. doi: [10.1177/1352458518798591](https://doi.org/10.1177/1352458518798591).
6. Fragoso YD, Finkelsztejn A, Kaimen-Maciel DR, et al. Long-term use of glatiramer acetate by 11 pregnant women with multiple sclerosis: A retrospective, multicentre case series. *CNS Drugs.* 2010;24:969–76. PubMed PMID: 20806993.
7. Hellwig K, Gold R. Glatiramer acetate and interferon-beta throughout gestation and postpartum in women with multiple sclerosis. *J Neurol.* 2011;258:502–3. PubMed PMID: 20878174.
8. Fragoso YD, Boggild M, Macias-Islas MA, et al. The effects of long-term exposure to disease-modifying drugs during pregnancy in multiple sclerosis. *Clin Neurol Neurosurg.* 2013;115:154–9. PubMed PMID: 22633835.

## **Substance Identification**

### **Substance Name**

Glatiramer

### **CAS Registry Number**

28704-27-0 147245-92-9

### **Drug Class**

Breast Feeding

Lactation

Immunologic Adjuvants