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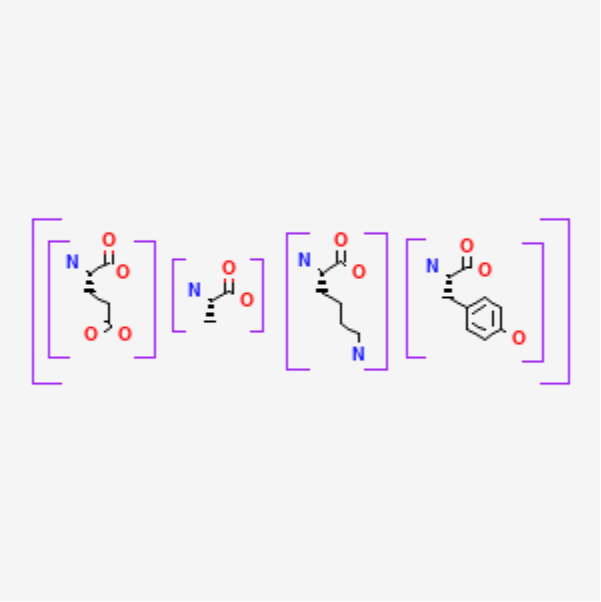
Glatiramer

Revised: November 15, 2023.

CASRN: 28704-27-0



Drug Levels and Effects

Summary of Use during Lactation

Glatiramer is the active portion of the drug, glatiramer acetate. Breastfeeding is not expected to result in clinically relevant exposure of the infant to the drug. Follow-up of infants indicates that maternal use of glatiramer acetate does not appear to 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.[1-8] No special precautions appear to be required during breastfeeding while using glatiramer and breastfeeding can resume immediately after injection.[9]

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. In a manufacturer-sponsored study, healthy volunteers were given 60 mg of glatiramer acetate subcutaneously. Blood samples were obtained at 5, 15, 30, 60, 120, 240, and 360 minutes after injection. Glatiramer was undetectable (<50 mcg/L) in the serum of 8 of 17 subjects; it was detectable for up to 30 minutes in 8 subjects and up to 360 minutes in one other. Assuming that milk levels equal peak serum levels, the authors estimated that in the worst-case scenario, an exclusively breastfed infant would receive a relative infant dose of 9% of the maternal weight-adjusted dosage in milk. However, the infant would be systemically exposed to a maximum of only 0.2% of the mother's dose when the poor oral bioavailability is considered.[10]

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.[11]

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.[12]

Among 1182 live birth pregnancies in the manufacturer's pharmacovigilance database, breastfeeding was reported for 14.3% of women (n = 169). During the first month after birth breastfeeding was reported in 10 mothers using 20 mg/mL daily and 64 using the 40 mg/mL three times weekly dosage regimen. Follow-up questionnaires were sent to patients or their healthcare providers at 1 and 12 months postpartum. Among 40 women who completed the 12-month questionnaires, 3 received the 20 mg/mL dose, 36 received the 40 mg/mL dose, and 1 received both doses. Of 27 women with known breastfeeding practices, exclusive breastfeeding for 4 or more months was reported for 17 (63.0%) respondents. Partial breastfeeding, defined as breastfeeding for less than 4 months or mixed breast and bottle feeding, was reported for ten (37.0%) mothers. The mean duration of exposure while breastfeeding was 7 months (SD = 4.3 months) with durations up to 13 months. Of 40 breastfeeding women, infant characteristics at birth and at approximately 12 months of age were available for 18 breastfed infants, all to the 40 mg/mL dose. The mean infant weight and length at birth and 12 months were within the normal range for the World Health Organization z-score and percentiles.[13]

In a retrospective, non-interventional, study from the German Multiple Sclerosis & Pregnancy Registry , 60 infants breastfed by mothers with multiple sclerosis treated with glatiramer were compared to 60 breastfed infants of mothers with MS not treated with a disease-modifying therapy. The median duration of breastfeeding during glatiramer use was 7 months (range 0.2 to 19.1 months). No difference was found in the number of hospitalizations for infection between the two groups up to 18 months of age. No differences in weight, length, or head circumference were seen between infants in the two cohorts up to 12 months of age.[7] A follow-up analysis found no difference in the number or types of serious adverse effects in infants between the two groups.[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

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Substance Identification

Substance Name

Glatiramer

CAS Registry Number

28704-27-0 147245-92-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Immunologic Adjuvants