



Omalizumab

Revised: November 15, 2023.

CASRN: 242138-07-4

Drug Levels and Effects

Summary of Use during Lactation

Preliminary evidence indicates that the amount in milk is very low. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] Many infants have been breastfed during maternal omalizumab therapy, with no increase in infectious complications. Omalizumab is considered acceptable to use during breastfeeding.[2,3] Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[4]

Drug Levels

Maternal Levels. A woman received omalizumab 5 weekly doses of omalizumab 150 mg subcutaneously during pregnancy until 28 weeks of gestation. Breastmilk omalizumab levels were determined on days 4 and 5 postpartum, which were 85 and 86 days after the last dose of omalizumab. Four concentrations in milk were below 2 mcg/L and one was just over 8 mcg/L.[5]

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

Effects in Breastfed Infants

A manufacturer-based omalizumab pregnancy registry has followed pregnant and nursing mothers for several years. Of 230 infants followed, 154 were breastfed while their mothers were taking omalizumab. Another 32 were breastfed without being exposed to the drug in milk and 44 were not breastfed. No difference in serious adverse events were seen among the three groups of infants. Infections occurred at a similar rate in all groups.[6]

Several case reports of infants being breastfed during maternal omalizumab therapy have been published. No adverse effects have been found.[7-11]

A woman with cystic fibrosis and severe, persistent asthma was started on omalizumab 600 mg subcutaneously every 2 weeks. She was maintained on this regimen for 5 years when she became pregnant. The regimen was

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continued during pregnancy and postpartum. She breastfed (extent not stated) for 8 months. At 10 months of age, her infant was in good health.[12]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Asthma) [Benralizumab](#), [Mepolizumab](#)

References

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Substance Identification

Substance Name

Omalizumab

CAS Registry Number

242138-07-4

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Allergic Agents

Anti-Asthmatic Agents

Antibodies, Monoclonal

Antibodies, Anti-Idiotypic