



Omalizumab

Revised: March 16, 2020.

CASRN: 242138-07-4

Drug Levels and Effects

Summary of Use during Lactation

Because omalizumab is a large protein molecule with a molecular weight of 145,058, the amount in milk is likely to be very low and absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. Many infants have been breastfed during maternal omalizumab therapy, with no increase in infectious complications. Omalizumab is considered acceptable to use during breastfeeding.[1]

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

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.[2]

Case reports of infants being breastfed during maternal omalizumab have been published. No adverse effects have been found.[3,4]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Asthma) Benralizumab, Mepolizumab

References

1. Türk M, Carneiro-Leao L, Kolkhir P, et al. How to treat patients with chronic spontaneous urticaria with omalizumab: Questions and answers. *J Allergy Clin Immunol Pract*. 2020;8:113–24. PubMed PMID: 31374358.
2. Lopez Leon, S, Kaufman DG, Howard M, et al. Safety outcomes among infants exposed to omalizumab via breastfeeding: Results from the Xolair Pregnancy Registry (Expect). *Pharmacoepidemiol Drug Saf* 2019;28 (Suppl 2):374-5. Abstract. doi: [10.1002/pds.4864](https://doi.org/10.1002/pds.4864).
3. Ensina LF, Cusato-Ensina AP, Camelo-Nunes IC, et al. Omalizumab as third-line therapy for urticaria during pregnancy. *J Investig Allergol Clin Immunol*. 2017;27:326–7. PubMed PMID: 29057743.
4. Gonzalez-Medina M, Curto-Barredo L, Labrador-Horrillo M, et al. Omalizumab use during pregnancy for chronic spontaneous urticaria (CSU): Report of two cases. *J Eur Acad Dermatol Venereol*. 2017;31:e245–e6. PubMed PMID: 27868240.

Substance Identification

Substance Name

Omalizumab

CAS Registry Number

242138-07-4

Drug Class

Breast Feeding

Lactation

Anti-Allergic Agents

Anti-Asthmatic Agents

Antibodies, Monoclonal

Antibodies, Anti-Idiotypic

