



Belimumab

Revised: April 15, 2024.

CASRN: 356547-88-1

Drug Levels and Effects

Summary of Use during Lactation

Preliminary information and a predictive model indicate that belimumab levels in milk are very low.[1] It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[2,3] If belimumab is required by the mother, it is not a reason to discontinue breastfeeding. Some professional guidelines consider belimumab to be acceptable during breastfeeding.[4,5] Until more data become available, belimumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant. Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[6]

Drug Levels

Maternal Levels. A postpartum woman with mixed connective tissue disease was started on intravenous belimumab 520 mg (10 mg/kg) every 2 weeks for 2 doses, then 520 mg monthly as well as hydroxychloroquine 200 to 400 mg daily. Belimumab milk concentrations were 0.12 mg/L at 2 weeks after the first dose and prior to the second dose, 0.17 mg/L on the following day, and 0.12 mg/L at 7 weeks after the second dose.[7]

Two lactating women with systemic lupus erythematosus who were receiving belimumab 200 mg subcutaneously every 2 weeks donated milk samples postpartum at starting at 3 to 4 days postpartum. Milk concentrations were highest at about 3 days after the dose at about 75 mcg/L in one woman and about 125 mcg/L in the other. At 7 days after the dose, milk levels remained relatively constant in the first woman and decreased to about 90 mcg/L in the second.[8]

A woman with systemic lupus erythematosus was started on belimumab 200 mg subcutaneously every two weeks and discontinued breastfeeding at 3 months postpartum. She continued to pump milk to avoid engorgement. Two milk samples were analyzed for belimumab. On day 14 after 2 doses of the drug, an evening milk sample contained 0.264 mg/L of belimumab and a second sample taken on day 28 before the fifth dose contained 0.885 mg/L.[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.

Attribution Statement: LactMed is a registered trademark of the U.S. Department of Health and Human Services.

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

Effects in Breastfed Infants

A woman with systemic lupus erythematosus was taking belimumab (dose not stated) for 1 year when she became pregnant. She received monthly belimumab infusions during pregnancy and continued postpartum, starting at 2 weeks postpartum. She breastfed her infant (extent not stated). No infant effects were mentioned. [10]

Effects on Lactation and Breastmilk

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

References

1. Stratigakis A, Paty D, Zou P, et al. A regression approach for assessing large molecular drug concentration in breast milk. *Reprod Breed* 2023;3:199-207. doi:10.1016/j.repbre.2023.10.003
2. Anderson PO. Monoclonal antibodies during breastfeeding. *Breastfeed Med* 2021;16:591-3. PubMed PMID: 33956488.
3. Sammaritano LR, Bermas BL, Chakravarty EE, et al. 2020 American College of Rheumatology Guideline for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases. *Arthritis Rheumatol* 2020;72:529-56. PubMed PMID: 32090480.
4. Göttestam Skorpen C, Hoeltzenbein M, Tincani A, et al. The EULAR points to consider for use of antirheumatic drugs before pregnancy, and during pregnancy and lactation. *Ann Rheum Dis* 2016;75:795-810. PubMed PMID: 26888948.
5. Russell MD, Dey M, Flint J, et al. British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: Immunomodulatory anti-rheumatic drugs and corticosteroids. *Rheumatology (Oxford)* 2023;62:e48-e88. PubMed PMID: 36318966.
6. Krysko KM, Dobson R, Alroughani R, et al. Family planning considerations in people with multiple sclerosis. *Lancet Neurol* 2023;22:350-66. PubMed PMID: 36931808.
7. Saito J, Yakuwa N, Ishizuka T, et al. Belimumab concentrations in maternal serum and breast milk during breastfeeding and the safety assessment of the infant: A case study. *Breastfeed Med* 2020;15:475-7. PubMed PMID: 32326740.
8. Saito J, Yakuwa N, Hosokawa Y, et al. Establishment of a measurement system to evaluate breast milk transfer of biological agents using dry filter paper: A multi-institutional study. *Br J Clin Pharmacol* 2024;90:146-57. PubMed PMID: 37548054.
9. Blomjous BS, de Boer MA, van Weissenbruch MM, et al. Concentrations of subcutaneously administered belimumab in human breast milk of a woman with systemic lupus erythematosus: a case report. *Lupus Sci Med* 2024;11:e001167. PubMed PMID: 38499356.
10. Danve A, Perry L, Deodhar A. Use of belimumab throughout pregnancy to treat active systemic lupus erythematosus: A case report. *Semin Arthritis Rheum* 2014;44:195-7. PubMed PMID: 25005336.

Substance Identification

Substance Name

Belimumab

CAS Registry Number

356547-88-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal