



Sarilumab

Revised: January 15, 2024.

CASRN: 1189541-98-7

Drug Levels and Effects

Summary of Use during Lactation

Because sarilumab is a large protein molecule with a molecular weight of about 150,000 Da, the amount in milk is likely to be 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] One infant was safely breastfed for 6 months after maternal sarilumab was resumed at 28 days postpartum. If sarilumab is required by the mother, it is not a reason to discontinue breastfeeding.[3] Until more data become available, sarilumab 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.[4]

Drug Levels

Maternal Levels. A lactating woman was receiving subcutaneous sarilumab 150 mg every 2 weeks for rheumatoid arthritis. After 5 doses of the drug, she donated 6 milk samples over a 28-day period. The peak concentration of about 160 mcg/L occurred on day 3 after the dose. By day 7, the milk sarilumab concentration decreased to about 110 mcg/L; on day 14, the milk concentration was about 75 mcg/L. The drug was undetectable in milk at 28 days after the dose.[5]

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

Effects in Breastfed Infants

A woman with rheumatoid arthritis refractory to etanercept took sarilumab 200 mg every two weeks during pregnancy until 37 weeks of gestation. She was also taking prednisolone 10 mg and tacrolimus 3 mg daily. She delivered a healthy infant at 38 weeks of gestation and breastfed her infant. Prednisolone was continued postpartum; tacrolimus was restarted at 7 days postpartum and sarilumab was restarted at 28 days postpartum. The mother continued to breastfeed until 6 months postpartum. The infant was vaccinated with multiple live vaccines after reaching six months old, including the Bacille-Calmette-Guerin vaccine, with no adverse effects.[6]

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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Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Rheumatoid Arthritis) [Adalimumab](#), [Certolizumab Pegol](#), [Etanercept](#), [Infliximab](#), [Tocilizumab](#)

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
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3. Götestam 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.
4. 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.
5. 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.
6. Mizutani S, Okunishi Y, Tamada T, et al. A woman with rheumatoid arthritis who successfully delivered a healthy child with continuous administration of sarilumab throughout pregnancy. *Intern Med* 2023;62:633-6. PubMed PMID: 35871593.

Substance Identification

Substance Name

Sarilumab

CAS Registry Number

1189541-98-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal

Antirheumatic Agents