



Rituximab

Revised: February 17, 2020.

CASRN: 174722-31-7

Drug Levels and Effects

Summary of Use during Lactation

Rituximab is a genetically engineered chimeric murine/human monoclonal antibody that targets CD20, a B-cell-specific surface antigen. The amount in milk is very low and absorption is unlikely because it is a protein with a molecular weight of 143,860, it is probably destroyed in the infant's gastrointestinal tract.[1,2] Although 2 breastfed infants apparently experienced no adverse effects during maternal use of rituximab, no long-term data are available. If rituximab is required by the mother, it is not a reason to discontinue breastfeeding.[3,4] Until more data become available, rituximab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant.[5-7] The manufacturer recommends that breastfeeding be discontinued during rituximab therapy and for 6 months after the last dose.

Drug Levels

Maternal Levels. A patient who had granulomatosis with polyangiitis received rituximab 1000 mg intravenously while exclusively breastfeeding her infant. Milk samples were collected daily for 4 days starting 7 days after the infusion. Milk rituximab concentrations averaged 0.5 mcg/L (range 0.4 to 0.6 mcg/L).[2]

Infant Levels. A woman received rituximab 375 mg/square meter once weekly for 4 weeks beginning at week 30 of gestation. Her infant was born at 40 weeks of gestation and was exclusively breastfed with no major health issues. At 4 months of age, trace amounts of rituximab heavy and light chains were detected, but not quantified, in the infant's serum. Whether the drug was acquired transplacentally or during breastfeeding was not determined.[8]

Effects in Breastfed Infants

A woman received rituximab 375 mg/square meter once weekly for 4 weeks beginning at week 30 of gestation. Her infant was born at 40 weeks of gestation and was exclusively breastfed with no major health issues. At 4 months of age, the infant's B-cell population and immunoglobulin levels did not appear to be affected.[9]

A woman received an IV infusion of 1000 mg of rituximab at about 3 months postpartum. Her infant who was fully breastfed had no serious infections during the lactation period and developed normally during a 1.5 year follow-up period.[2]

Four infants who were breastfed by mothers who received either 500 mg or 1000 mg of rituximab were followed for 8 to 12 months. One of the infants' mother receive 2 doses of rituximab at 0.5 and 7 months postpartum. All infants had typical childhood infections, but none were serious. Growth and development was normal in all 4 infants for up to 8 to 12 months of age.[8]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Multiple Sclerosis) Glatiramer, Immune Globulin, Interferon Beta (Rheumatoid Arthritis) Auranofin, Gold Sodium Thiomalate, Hydroxychloroquine, Infliximab, Methotrexate, Penicillamine, Sulfasalazine

References

1. Pistilli B, Bellettini G, Giovannetti E, et al. Chemotherapy, targeted agents, antiemetics and growth-factors in human milk: How should we counsel cancer patients about breastfeeding? *Cancer Treat Rev.* 2013;39:207–11. PubMed PMID: 23199900.
2. Bragnes Y, Boshuizen R, de Vries A, et al. Low level of rituximab in human breast milk in a patient treated during lactation. *Rheumatology (Oxford).* 2017;56:1047–8. PubMed PMID: 28339781.
3. Gotestam 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. Whittam DH, Tallantyre EC, Jolles S, et al. Rituximab in neurological disease: principles, evidence and practice. *Pract Neurol.* 2019;19:5–20. PubMed PMID: 30498056.
5. Almas S, Vance J, Baker T, et al. Management of multiple sclerosis in the breastfeeding mother. *Mult Scler Int.* 2016;2016:6527458. PubMed PMID: 26966579.
6. Keeling SO, Oswald AE. Pregnancy and rheumatic disease: "by the book" or "by the doc". *Clin Rheumatol.* 2009;28:1–9. PubMed PMID: 18987777.
7. Ostensen M. Management of early aggressive rheumatoid arthritis during pregnancy and lactation. *Expert Opin Pharmacother.* 2009;10:1469–79. PubMed PMID: 19505214.
8. Krysko KM, LaHue SC, Anderson A, et al. Minimal breast milk transfer of rituximab, a monoclonal antibody used in neurological conditions. *Neurol Neuroimmunol Neuroinflamm.* 2020;7:e637. PubMed PMID: 31719115.
9. Jin J, Mills J, Conboy E, et al. In utero rituximab: Detection of rituximab in an infant at 4 months of age. *Ann Allergy Asthma Immunol.* 2014;113:A14–Abstract 36.

Substance Identification

Substance Name

Rituximab

CAS Registry Number

174722-31-7

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal

Antirheumatic Agents

Antineoplastic Agents