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Natalizumab

Revised: July 20, 2019.

CASRN: 189261-10-7

Drug Levels and Effects

Summary of Use during Lactation

Natalizumab is excreted into breastmilk in some, but not all, women. The time of the peak level in breastmilk is variable, but might be as long as 6 months. Because natalizumab is a large protein molecule with a molecular weight of about 149,000, absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. Some experts recommend avoiding breastfeeding with natalizumab, while others do not.[1][2][3] Until more data become available, natalizumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant.

Drug Levels

Maternal Levels. A woman was started on natalizumab 300 mg intravenously while nursing her 11.5 month old infant. Multiple milk levels were obtained almost daily over the 50 days after she received a dose on day 1 and another on day 29. Natalizumab was undetectable (<250 mcg/L) in breastmilk until day 14 when a concentration of 333 mcg/L was measured. A peak level of 1.01 mg/L was detected on day 20. On day 29, the natalizumab milk level was 491 mcg/L when the second dose was given. Milk levels increased to a maximum of 2.83 mg/L on day 50 when breastmilk collection ceased. The authors estimated that a fully breastfed infant would receive a weight-adjusted dosage of 1.7% using the average level over the 50 days and 5.3% using the peak milk level. However, in this study, steady-state was probably not achieved, so the amounts in breastmilk could continue to increase over a period of about 6 months.[4]

Natalizumab was detected in the breastmilk in one of two mothers of newborn infants at a concentration of 1.89 mg/L just prior to a dose. The previous maternal dose had been given during pregnancy, but the maternal dose and time since the previous dose were not reported in the abstract. The other mother had no detectable natalizumab in breastmilk.[5]

Four women who were receiving natalizumab for multiple sclerosis donated breastmilk samples at various times after infusion of 300 mg of the drug up to 5.5 months postpartum. Concentrations of free natalizumab in breastmilk ranged from 2 to 412 mcg/L. One mother had no detectable natalizumab at any time and another had only trivial amounts at 6 time points. Variability in milk levels was considerable, but inversely correlated with the

time since the infusion. Regression indicated that on average, natalizumab was cleared from milk at about 35 days after a dose, although it was detectable at very low levels beyond this time in 2 samples.[6]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 2 women receiving natalizumab provided milk samples at 1, 12, 24, and 48 hours after drug administration. One woman had natalizumab in breastmilk at 12 hours and 24 hours in concentrations of 0.26 and 0.46 mg/L, respectively.[3]

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

Effects in Breastfed Infants

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 8 women received natalizumab while breastfeeding their infants. Among those who received natalizumab or another biologic agent while breastfeeding, infant growth, development or infection rate was no different from infants whose mothers received no treatment. An additional 68 women received a biologic agent plus a thiopurine. Infant outcomes were similar in this group.[3]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Inflammatory Bowel Disease) Budesonide, Infliximab, Mesalamine, Prednisone; (Multiple Sclerosis) Glatiramer, Immune Globulin, Interferon beta

References

1. Yarur A, Kane SV. Update on pregnancy and breastfeeding in the era of biologics. Dig Liver Dis. 2013;45:787-94. PubMed PMID: 23474350.
2. Matro R, Martin CF, Wolf D et al. Exposure concentrations of infants breastfed by women receiving biologic therapies for inflammatory bowel diseases and effects of breastfeeding on infections and development. Gastroenterology. 2018;155:696-704. PubMed PMID: 29857090.
3. Mahadevan U , Robinson C, Bernasko N et al. Inflammatory bowel disease in pregnancy clinical care pathway: A report from the American Gastroenterological Association IBD Parenthood Project Working Group. Gastroenterology. 2019;156:1508-24. PubMed PMID: 30658060.
4. Baker TE, Cooper SD, Kessler L, Hale TW. Transfer of natalizumab into breast milk in a mother with multiple sclerosis. J Hum Lact. 2015;31:233-6. PubMed PMID: 25586712.
5. Hainke U, Sehr T, Eisele JC et al. Natalizumab: Passage into breast milk and neonatal blood. Mult Scler. 2015;23:690. Abstract EP1324 DOI: 10.1177/1352458515602642.
6. Proschmann U, Thomas K, Thiel S et al. Natalizumab during pregnancy and lactation. Mult Scler. 2018;24:1627-34. PubMed PMID: 2885768.

Substance Identification

Substance Name

Natalizumab

CAS Registry Number

189261-10-7

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal

Anti-Inflammatory Agents