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Certolizumab Pegol

Revised: June 15, 2024.

CASRN: 428863-50-7

Drug Levels and Effects

Summary of Use during Lactation

Certolizumab is excreted into breastmilk in some, but not all, women in small amounts. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] Polyethylene glycol is not excreted into breastmilk.[2] Most experts and professional guidelines consider certolizumab pegol to be acceptable to use during breastfeeding and some consider it to be a first-line treatment for moderate to severe psoriasis.[3-16]

Drug Levels

Maternal Levels. One woman received certolizumab pegol 400 mg by subcutaneous injection every 4 weeks during pregnancy and postpartum. The last dose during pregnancy was 1 week prior to delivery. Breastmilk samples were collected 1 and 2 weeks postpartum and 4 hours, 3 days and 6 days after the first postpartum dose which was given at 3 weeks postpartum. Certolizumab was undetectable (<410 mcg/L) in all 5 samples.[17]

Two women were receiving certolizumab pegol 200 mg every two weeks. Certolizumab was undetectable (<0.6 mg/L) in breastmilk one hour after the dose in both women and 4 hours after the dose in one of them.[18]

Seventeen nursing mothers who were taking certolizumab pegol for an inflammatory condition and were at least 6 weeks postpartum had certolizumab measured in their breastmilk at least 8 times over a dosage interval. The maternal dose was 200 mg every 2 weeks in 16 women and 400 mg every 4 weeks in another. Out of 137 breastmilk samples, 77 had no detectable certolizumab and 4 mothers had no detectable (<32 mcg/L) certolizumab in milk at any time point, including the mother who received the 400 mg dose. Of the 13 other mothers, the highest concentrations found were 76 mcg/L, which was found in one woman at 6 and 8 days after the dose, and 65 and 66 mcg/L in another at 4 and 6 days after the dose, respectively. All other mothers with detectable certolizumab had milk levels that were less than 64 mcg/L. The median time of peak milk levels was 5.05 days (range 2.9 to 11.9 days). The estimated average daily infant dose ranged from 0 to 0.0104 mg/kg daily. No measurable levels of total polyethylene glycol were detected in 134 of 137 breast milk samples; 3 samples had indeterminate results upon retesting.[2]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 13 women receiving certolizumab pegol provided milk samples at 1, 12, 24, and 48 hours after drug administration. Some also provided samples at 72, 96, 120, and 168 hours after drug administration. Three of the women had detectable (>0.01 mg/L) certolizumab levels in milk. Peak concentrations in breastmilk ranged from 0.27 to 0.29 mg/L and occurred at 12 to 48 hours after the dose.[8]

A woman in Japan with rheumatoid arthritis was treat with certolizumab pegol (dosage not stated) beginning at 28 weeks of pregnancy and continuing postpartum. Breastmilk samples taken before delivery, at delivery, and 4 and 8 weeks postpartum all contained unmeasurable (<0.1 mg/L) amounts of certolizumab.[19]

Infant Levels. One woman received certolizumab pegol 400 mg by subcutaneous injection every 4 weeks during pregnancy and postpartum. The last dose during pregnancy was 1 week prior to delivery. At birth, her infant had a serum concentration 1.02 mg/L. At one month of age, her breastfed (extent not stated) infant had a serum concentration of 0.84 mg/L seven days after the previous injection.[17,19]

In a study reported in the product information, plasma certolizumab concentrations were collected 4 weeks after birth in 9 breastfed infants whose mothers had been currently taking certolizumab pegol (regardless of being exclusively breastfed or not). Certolizumab was not measurable (<32 mcg/L) in infant plasma.

Effects in Breastfed Infants

Eight women who received certolizumab pegol during pregnancy and postpartum breastfed (extent not stated) their infants. No mention was made of side effects in the infants.[17]

Seventeen mothers received certolizumab pegol for an inflammatory condition and breastfed their infants. During a study period starting at least 6 weeks postpartum and after at least 3 doses of certolizumab pegol, 8 of the infants experienced 11 adverse effects. None of the infants had any unusual or serious adverse reactions attributed to the drug and all effects were consistent with events typically experienced by infants of the same age, such as upper respiratory infection, *Candida* infection, or vomiting.[19]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 54 women received certolizumab pegol while breastfeeding their infants. Among those who received certolizumab or another biologic agent while breastfeeding, infant growth, development or infection rate was no different from infants whose mothers received no treatment. An additional 67 women received a biologic agent plus a thiopurine. Infant outcomes were similar in this group.[8]

Six women being treated with certolizumab pegol for uveitis during pregnancy and postpartum breastfed their infants (extent not sated). One of the mothers also took hydroxychloroquine. In 6 months of follow-up, no infants had any infections and all had inactivated vaccines specified in the Spanish national immunization program (hepatitis B, diphtheria, tetanus and acellular pertussis [DTaP], inactivated poliovirus, *Haemophilus influenzae* type B conjugate, pneumococcal conjugate and meningococcal C conjugate). One of the infants also received rotavirus vaccine. No complications were seen with any of the vaccines.[20]

Three women were treated with certolizumab, two during pregnancy and breastfeeding and one during breastfeeding alone. Infant follow-up at 6, 18 and 32 months, respectively, found no adverse reactions and normal growth and neurodevelopment in the infants.[21]

A national prospective registry of patients with rheumatic diseases who were treated with biological DMARDs was conducted in Spain. One whose mother was taking certolizumab was breastfed (extent not stated) with no mild or severe adverse events reported in the infant.[22]

A retrospective study of mothers in Spain taking certolizumab pegol for psoriasis found 11 women who breastfed (extent not stated) their infants during therapy. No adverse events were reported in breastfed infants. [23]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Inflammatory Bowel Disease) Adalimumab, Infliximab; (Rheumatoid Arthritis) Adalimumab, Etanercept, Infliximab, Tocilizumab

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Substance Identification

Substance Name

Certolizumab Pegol

CAS Registry Number

428863-50-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal

Immunoglobulin Fab Fragments

Antirheumatic Agents

Gastrointestinal Agents

Tumor Necrosis Factor Inhibitors