



Certolizumab Pegol

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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. Absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. Most experts consider certolizumab to be probably safe during breastfeeding.[1][2][3][4][5][6][7][8][9][10][11] The European Medicines Agency has deemed certolizumab pegol acceptable to use during breastfeeding.

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.[12]

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.[3]

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 (<0.032 mg/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 0.076 mg/L, which was found in one woman at 6 and 8 days after the dose, and 0.065 and 0.066 mg/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 0.064 mg/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. The median weight-adjusted relative infant dosage was calculated by the authors to be 0.15% (range 0.04 to 0.3%). No measurable levels of total polyethylene glycol were detected in 134 of 137 breast milk samples; 3 samples had indeterminate results upon retesting.[13]

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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. Two women had undetectable milk adalimumab levels over a week of monitoring.[9]

A woman in Japan with rheumatoid arthritis was treated 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 (<100 mcg/L) amounts of certolizumab.[14]

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.[12][15]

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.[12]

Seventeen mothers took 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, candidal infection, or vomiting.[13]

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.[9]

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](#)

References

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Substance Identification

Substance Name

Certolizumab Pegol

CAS Registry Number

428863-50-7

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal

Immunoglobulin Fab Fragments

Antirheumatic Agents

Gastrointestinal Agents