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Adalimumab

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CASRN: 331731-18-1

Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that maternal adalimumab injections produce low levels in breastmilk. Because adalimumab is a large protein molecule, it is likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] Adalimumab was undetectable in the serum of some breastfed infants and some information indicates that adalimumab does not adversely affect the nursing infant. In mothers who received adalimumab during pregnancy, continued use while breastfeeding does not prolong adalimumab elimination by the infant.[2] Most experts and professional guidelines consider adalimumab to be acceptable to use during breastfeeding.[3-13] Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[14]

Drug Levels

Maternal Levels. One woman received a single 40 mg of adalimumab subcutaneously at 4 weeks postpartum. Milk samples were obtained every 2 days for 8 days. A peak milk adalimumab level of 31 mcg/L was detected on day 6 after injection. Milk levels on days 5 and 8 were about 10 mcg/L.[15]

Two women received adalimumab 40 mg subcutaneously for treatment of inflammatory bowel disease at unstated intervals. The first woman received the drug during pregnancy and postpartum. At 21 weeks postpartum and 7 days after the previous dose, her breastmilk adalimumab was 4.83 mcg/L while her serum level was 6.7 mg/L. In the second woman, the milk adalimumab concentration at 8 weeks postpartum and 9 days after the last dose was 4.88 mcg/L with a simultaneous serum concentration of 5.5 mg/L.[16]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 21 women receiving adalimumab 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. Two of the women had detectable (>0.01 mg/L) adalimumab levels in milk. Peak concentrations in breastmilk were 0.45 and 0.71 mg/L and occurred at 12 to 24 hours after the dose. Seven women had undetectable milk adalimumab levels over a week of monitoring.[17]

Infant Levels. A woman received adalimumab 40 mg subcutaneously at unstated intervals while breastfeeding (extent not stated). At 8 weeks postpartum and 9 days after the prior dose, the infant had an undetectable (<0.65 mcg/L) adalimumab serum concentration.[16]

A pregnant woman received adalimumab 40 mg every 2 weeks for Crohn's disease until week 16 of pregnancy. Her infant was exclusively breastfed until 4 months of age and the drug was reinstituted on day 24 postpartum. At 3 months of age, adalimumab was undetectable in the infant's serum.[18]

Effects in Breastfed Infants

One woman with Crohn's disease received adalimumab 40 mg subcutaneously every week during pregnancy and breastfeeding (extent not stated). Her infant demonstrated normal growth and development at 6 months of age.[19] The authors reported a brief follow-up stating that the woman also breastfed her second infant during adalimumab therapy with no adverse consequences.[20]

Another woman with Crohn's disease received adalimumab 40 mg subcutaneously every 2 weeks during pregnancy and breastfeeding (extent not stated). Her infant demonstrated normal growth and development at 6 months of age.[21]

Two women nursed their infants (extent not stated) while receiving adalimumab 40 mg subcutaneously at unstated intervals for inflammatory bowel disease. They breastfed for at least 21 weeks and 8 weeks, respectively, but the total duration was not stated. At 14.5 and 15 months of age, respectively, neither infant had any signs of adverse drug reactions, allergic reactions or severe infections leading to hospitalization. Developmental milestones were reached on time by both infants.[16]

A pregnant woman received adalimumab 40 mg every 2 weeks for Crohn's disease until week 16 of pregnancy. Her infant was exclusively breastfed until 4 months of age and the drug was reinstituted on day 24 postpartum. At 7 months of age, the infant was healthy with normal growth and development. The infant had no infections requiring antibiotics or hospitalization.[18]

A case-control study of women with chronic arthritic conditions found 2 women who received adalimumab during pregnancy and lactation (extent not stated). No differences were observed in the 2 infants' growth parameters, developmental milestones, vaccinations and diseases in the first year of life compared to those not exposed to the drugs with lactation.[22]

A woman receiving adalimumab for severe psoriasis breastfed 2 infants following 2 pregnancies. No adverse effects were reported in the infant, although the dosage of adalimumab and the extent of breastfeeding were not reported.[23]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 99 women received adalimumab while breastfeeding their infants. Among those who received adalimumab 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.[17]

A national prospective registry of patients with rheumatic diseases who were treated with biological DMARDs was conducted in Spain. One whose mother was taking adalimumab was breastfed (extent not stated) with no mild or severe adverse events reported in the infant.[24]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Inflammatory Bowel Disease) Certolizumab Pegol, Infliximab; (Psoriasis) Etanercept; Infliximab, Phototherapy, Tretinoin; (Rheumatoid Arthritis) Certolizumab Pegol, Etanercept, Infliximab

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Substance Identification

Substance Name

Adalimumab

CAS Registry Number

331731-18-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal, Humanized

Antirheumatic Agents

Dermatologic Agents

Gastrointestinal Agents

Anti-Inflammatory Agents

Tumor Necrosis Factor Inhibitors