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Etanercept

Revised: May 1, 2019.

CASRN: 185243-69-0

Drug Levels and Effects

Summary of Use during Lactation

Etanercept is minimally excreted into breastmilk and poorly absorbed by the infant, which would be expected because of its high molecular weight of approximately 150,000. However, long-term follow-up data on infants breastfed during maternal etanercept use are not available. The risk of adverse effects in older infants is not known, but thought to be unlikely.[1] Most experts feel that the drug is a low risk to the nursing infant and can be given during breastfeeding.[2][3][4][5][6][7]

Drug Levels

Maternal Levels. One woman was receiving etanercept 25 mg subcutaneous injections twice weekly. The mother was secreting small amounts of milk, but not breastfeeding. On day 44 after delivery the trough milk etanercept level before the fifth dose was 50 mcg/L. A milk etanercept level one day after the fifth injection was 75 mcg/L and milk levels declined thereafter.[1]

A woman received etanercept 25 mg subcutaneously twice weekly during pregnancy and lactation. At 12 weeks postpartum, a breastmilk sample taken at an unspecified time after a dose was 3.5 mcg/L. Her serum etanercept concentration at the same time was 2872 mcg/L.[8]

A woman with ankylosing spondylitis received etanercept 25 mg subcutaneously once weekly during pregnancy and postpartum. Breastmilk concentrations were measured daily from day 40 to day 47 postpartum following a dose on day 40. Breastmilk concentrations ranged from 2 to 5 mcg/L; the high concentration of 5 mcg/L occurred on day 43 and corresponded with the highest maternal serum etanercept concentration. By day 47, etanercept was not detectable in breastmilk (<2 mcg/L).[9]

A woman with rheumatoid arthritis began etanercept 25 mg subcutaneously twice a week at 3 months postpartum and later switched to a dose of 50 mg subcutaneously once a week. Breastmilk samples were collected over a 2-month period. Before the first dose, the milk level was <1.5 mcg/L. Etanercept milk levels 24 and 48 hours after 25 mg doses were 4.48 and 5.25 mcg/L, respectively. Etanercept milk levels 24 and 72 hours after 50 mg doses were 4.48 and 7.5 mcg/L.[10]

Infant Levels. An infant was born to a mother who received etanercept 25 mg subcutaneously twice a week during pregnancy and postpartum. At birth, the cord blood etanercept concentration was 81 mcg/L. The infant was completely breastfed. At 1 week postpartum, the infant's serum etanercept level was 21 mcg/L, at 3 weeks postpartum it was 2 mcg/L, and at 12 weeks it was undetectable, despite a breastmilk concentration of 3.5 mcg/L at that time.[8]

An infant was born to a mother with ankylosing spondylitis who received etanercept 25 mg subcutaneously once weekly during pregnancy and postpartum. The infant was fed about 50% breastmilk during days 40 to 47 postpartum following a maternal dose on day 40. Infant serum etanercept concentrations were 40 mcg/L at birth and <4 mcg/L on days 41 to 43.[9]

Effects in Breastfed Infants

A woman with rheumatoid arthritis began etanercept 25 mg subcutaneously twice a week at 3 months postpartum and later switched to a dose of 50 mg subcutaneously once a week. Her infant was breastfed (extent not stated) until 6 months of age. The infant was reportedly healthy at 3 years of age.[10]

A case-control study of women with chronic arthritic conditions found 5 women who received etanercept during pregnancy and lactation (extent not stated). No differences were observed in the 5 infants' growth parameters, developmental milestones, vaccinations and diseases in the first year of life compared to those not exposed to the drugs with lactation.[11]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Psoriasis) Adalimumab, Infliximab, Phototherapy, Tretinoin; (Rheumatoid Arthritis) Adalimumab, Certolizumab Pegol, Infliximab

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Substance Identification

Substance Name

Etanercept

CAS Registry Number

185243-69-0

Drug Class

Breast Feeding

Lactation

Antirheumatic Agents

Dermatologic Agents

Gastrointestinal Agents