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#### **Anakinra**

Revised: September 15, 2023.

CASRN: 143090-92-0

## **Drug Levels and Effects**

## **Summary of Use during Lactation**

Anakinra is the pharmaceutical name for recombinant human interleukin-1 receptor antagonist (IL-1Ra). IL-1Ra is a normal component of human milk where it may play a role as an anti-inflammatory agent. Several infants have been breastfed during maternal anakinra therapy, occasionally in conjunction with colchicine, with no obvious adverse effects. If anakinra is required by the mother, it is not a reason to discontinue breastfeeding. [1-3]

## **Drug Levels**

Maternal Levels. The concentration of IL-1Ra in colostrum in 88 normal mothers was 672 ng/L, which was higher than the plasma concentration. Mature milk levels were lower than those in colostrum. Samples collected over a period of 2 to 6 months postpartum indicated that mothers continued to excrete IL-1Ra during this time. [4] Mothers with acute mastitis had slightly higher average levels of IL-1Ra than levels after recovery, but the median values were the same. The levels found in these mothers were the same as those of control mothers.[5]

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

#### **Effects in Breastfed Infants**

A woman was receiving anakinra 100 mg daily for adult-onset Still's disease during pregnancy and lactation. Her breastfed (extent not stated) infant gained wight and appeared to have normal psychomotor development during an unspecified follow-up period.[6]

Among a cohort of 18 women with term pregnancies treated with anakinra for cryopyrin-associated periodic syndromes during pregnancy, 3 of the women breastfed their infants (extent not stated) for periods of <1 month, 3 months and 1 year. No adverse neonatal outcomes were reported.[7]

**Disclaimer:** Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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In an international multicenter study of mothers exposed to interleukin-1 receptor antagonists, 10 babies were breastfed (extent not stated) by mothers receiving anakinra for up to 10 months. No infections or developmental abnormalities were reported.[8] Three of the cases had been reported previously in reference[7].

Of 5 women who took anakinra during pregnancy, two breastfed their infants while continuing to receive anakinra 100 mg daily. No serious infections were reported and development was normal.[9]

A woman was treated with anakinra 100 mg subcutaneously once daily and oral colchicine 1 mg twice daily during pregnancy and postpartum for familial Mediterranean fever while she breastfed her infant (extent not stated). At 9 months of age, the infant's development was within normal range. The routine vaccination schedule for the baby was being performed on time and there was no history of infection in the infant.[10]

A woman with recurrent pericarditis was treated with subcutaneous anakinra 100 mg once weekly beginning in the fifth month of pregnancy and continuing postpartum. She also took colchicine 0.5 mg daily. She delivered twins by cesarean section at 36 weeks of gestation and breastfed (extent not stated) her infants up to 18 months of age. No health problems were noted in the infants up to 18 months of age. [11]

#### **Effects on Lactation and Breastmilk**

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

## **Alternate Drugs to Consider**

(Rheumatoid Arthritis) Adalimumab, Certolizumab Pegol, Etanercept, Infliximab, Tocilizumab

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# **Substance Identification**

### **Substance Name**

Anakinra

# **CAS Registry Number**

143090-92-0

# **Drug Class**

**Breast Feeding** 

Lactation

Milk, Human

Antirheumatic Agents

Cytokines