



## Ustekinumab

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CASRN: 815610-63-0

## Drug Levels and Effects

### Summary of Use during Lactation

Limited published information is available on the clinical use of ustekinumab during breastfeeding. It is usually either not detectable in breastmilk or detectable at very low levels. Absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. If ustekinumab is required by the mother, it is not a reason to discontinue breastfeeding and some experts consider it a good choice in nursing women with psoriasis.[1][2][3] Until more data become available, ustekinumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant.

Ustekinumab is a human immunoglobulin G1 (IgG1) kappa antibody. Holder pasteurization (62.5 degrees C for 30 minutes) decreases the concentration of endogenous immunoglobulin G by up to 79%.[4][5][6] A study of 67 colostrum samples that underwent Holder pasteurization found that IgG amounts decreased by 34 to 40%. Specific IgG subclasses decreased by different amounts, with IgG1 activity decreasing by about 37%.[7] None of the studies measured IgG activity. Ustekinumab is unstable in breastmilk, with up to a 26% decrease in drug concentration when stored for 24 hours at room temperature.[8]

### Drug Levels

*Maternal Levels.* In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 6 women receiving ustekinumab 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. Four of the women had detectable (>0.01 mg/L) ustekinumab levels in milk. Peak concentrations in breastmilk ranged from 0.72 to 1.57 mg/L and occurred at 12 to 72 hours after the dose. Only 3 of the women had a detectable concentration in milk beyond 48 hours.[9]

A woman with treatment-refractory Crohn's disease was treated during pregnancy with ustekinumab until the third trimester. It was reinitiated 7 weeks postpartum with a loading dose of 390 mg intravenously, then 90 mg every 8 weeks. A breastmilk sample taken 16 weeks after the dose was 3.2 mg/L. After the third dose, breastmilk levels of ustekinumab were 0.82 mg/L within the first day after the dose, 0.18 mg/L at 3 weeks after the third dose and 0.16 mg/L at 4 weeks after the third dose.[8]

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

## Effects in Breastfed Infants

One woman receiving ustekinumab for severe psoriasis breastfed her infant. No adverse effects were reported in the infant, although the dosage of ustekinumab and the extent of breastfeeding were not reported.[10]

In a multi-center study of women with inflammatory bowel disease in pregnancy (the PIANO registry), 6 women received a ustekinumab while breastfeeding their infants. Among those who received ustekinumab 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.[9]

A woman with treatment-refractory Crohn's disease was treated during pregnancy with ustekinumab until the third trimester. It was reinitiated 7 weeks postpartum with a loading dose of 390 mg intravenously, then 90 mg every 8 weeks. She breastfed her infant (extent and duration not reported). Follow-up of the infant at 12 months of age was normal.[8]

A woman with severe psoriasis was treated with ustekinumab 45 mg subcutaneously every 12 weeks until pregnancy was confirmed. After delivery ustekinumab was restarted while she was breastfeeding (extent and duration not stated). The infant reportedly had no complications and a normal growth curve.[11]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

(Psoriasis) [Adalimumab](#), [Etanercept](#), [Infliximab](#), [Phototherapy](#), [Tretinoin](#)

## References

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## Substance Identification

### Substance Name

Ustekinumab

### CAS Registry Number

815610-63-0

### Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal

Dermatologic Agents