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Vedolizumab

Revised: March 16, 2020.

CASRN: 943609-66-3

Drug Levels and Effects

Summary of Use during Lactation

Some information indicates that maternal vedolizumab injections appear to produce low levels in breastmilk and to not adversely affect the nursing infant. Because vedolizumab is a large protein molecule with a molecular weight of about 147,000, absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. Most experts feel that the drug is probably safe during nursing.[1,2] Until more data become available, vedolizumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant.

Drug Levels

Maternal Levels. Five lactating women who were receiving vedolizumab for inflammatory bowel disease donated milk samples at various times afer receiving a dose of 300 mg intravenously. Four were on maintenance therapy every 1 to 2 months and 1 was in the induction phase and had received 2 doses of the drug 2 weeks apart. Peak breastmilk levels occurred from day 2 to 4 after the dose with a median of day 3. Peak milk concentrations averaged 354 mcg/L (range 108 to 478 mcg/L). One woman collected milk daily for 15 days. Her breastmilk levels slowly decreased from a peak of 405 mcg/L on day 3 to 101 mcg/L on day 15.[3]

Five nursing mothers were receiving vedolizumab 300 mg intravenously at unspecified intervals for inflammatory bowel disease. Breastmilk samples were collected before a dose, 30 min after a dose and twice daily thereafter for up to 14 days. Trough samples contained 124 to 228 mcg/L of vedolizumab. Most breastmilk levels were between 150 and 250 mcg/L The highest breastmilk vedolizumab milk levels were variable and ranged from 196 to 318 mcg/L on days 3 through 7. Using the highest level measured, the authors calculated that an infant would receive 0.048 mg/kg of vedolizumab daily (by mouth).[4]

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

Effects in Breastfed Infants

Eight women who were receiving vedolizumab for inflammatory bowel disease were breastfeeding their infants (extent not stated). Dosages were 300 mg intravenously, at 1 to 2 month intervals for 6 and starting during

induction for 2 women. No increase in general or gastrointestinal tract infections were seen in the newborns up to 10 months of age and all infants reached their development milestones.[3]

Five infants were breastfed by mothers receiving vedolizumab 300 mg intravenously at regular intervals. The infants all had normal developmental milestones at 3.5 to 10 months of age. All of the infants routine inactive vaccines without complications.[4]

A multicenter, retrospective study in Belgium reported on women with inflammatory bowel disease during pregnancy and postpartum who received vedolizumab (n = 23). Twelve infants were breastfed by their mothers and were followed for a median of 23 weeks (IQR 10 to 60 weeks). Twenty of the 23 infants were vaccinated with the standard Belgian protocol, with 9 also receiving rotavirus vaccination. No serious infections or malignancies were reported.[5] In an extension of this study, 70 women who received vedolizumab were compared to those who received a TNF antagonist (n = 162) and to those who received no biological or immunologic therapy (n = 163). Sixty-two percent of women on vedolizumab breastfed their infants compared to 60% and 64% in the other groups. No malignancies were reported in any of the children during the first year of life and the number of infant infections were not statistically different between the groups. The extent of breastfeeding and postpartum dosage regimens were not stated.[6]

Effects on Lactation and Breastmilk

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

References

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Substance Identification

Substance Name

Vedolizumab

CAS Registry Number

943609-66-3

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal, Humanized

Gastrointestinal Agents