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Bezlotoxumab

Revised: December 3, 2018.

CASRN: 1246264-45-8

Drug Levels and Effects

Summary of Use during Lactation

No information is available on the clinical use of bezlotoxumab during breastfeeding. Because bezlotoxumab is a large protein molecule with a molecular weight of about 148,200 the amount in milk is likely to be very low and absorption is unlikely because it is probably destroyed in the infant's gastrointestinal tract. Until more data become available, bezlotoxumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant. The manufacturer recommends that breastfeeding be discontinued during bezlotoxumab therapy.

Bezlotoxumab is a human immunoglobulin G1 (IgG1) antibody. Holder pasteurization (62.5 degrees C for 30 minutes) decreases the concentration of endogenous immunoglobulin G in mature milk by 60 to 79%.[1][2] 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%.[3] None of the studies measured IgG activity.

Drug Levels

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

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

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

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

References

1. Koenig A, de Albuquerque Diniz EM, Barbosa SF et al. Immunologic factors in human milk: The effects of gestational age and pasteurization. J Hum Lact. 2005;21:439-43. PubMed PMID: 16280560.

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 .

- 2. Adhisivam B, Vishnu Bhat B, Rao K et al. Effect of Holder pasteurization on macronutrients and immunoglobulin profile of pooled donor human milk. J Matern Fetal Neonatal Med. 2018;1-4. PubMed PMID: 29587541.
- 3. Rodriguez-Camejo C, Puyol A, Fazio L et al. Antibody profile of colostrum and the effect of processing in human milk banks: Implications in immunoregulatory properties. J Hum Lact. 2018;34:137-47. PubMed PMID: 28586632.

Substance Identification

Substance Name

Bezlotoxumab

CAS Registry Number

1246264-45-8

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal