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Ipilimumab

Revised: December 3, 2018.

CASRN: 477202-00-9

Drug Levels and Effects

Summary of Use during Lactation

The amount of ipilimumab in breastmilk appears to be very low, but it may increase with subsequent doses during a treatment cycle. Absorption from the infant's gastrointestinal tract is unknown. Because ipilimumab is a large protein molecule with a molecular weight of 148,000, absorption is unlikely after the first few weeks postpartum, and it will probably be destroyed in the infant's gastrointestinal tract. Until more data become available, ipilimumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant. The manufacturer recommends that breastfeeding be discontinued during ipilimumab therapy and for 3 months after the last dose.

Ipilimumab 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%.[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. A woman with recurrent malignant melanoma was treated with ipilimumab 3 mg/kg intravenously over 90 minutes once every 3 weeks for 4 doses, beginning soon after delivery. Breast milk and serum samples were collected before she began therapy and at various times over the first 2 dosage intervals. A total of 26 daily breastmilk samples were obtained. Breastmilk levels of ipilimumab were at their highest of about 90 mcg/L at 10 days after the first infusion, and were lowest at 41 mcg/L at the time of the second infusion, 19 days after the first infusion. A peak milk level of 147 mcg/L was reached 4 days after the second infusion. It was apparent that accumulation took place after the second dose. The authors estimated that a fully breastfed infant would ingest a total of 4.5 mg of ipilimumab over a 4 month treatment cycle.[1] Using the author's average and peak milk concentrations, the average and maximum weight-adjusted percentage of maternal dosage would be 0.38% and 0.74%, respectively.

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

Effects in Breastfed Infants

A woman with recurrent malignant melanoma was treated with ipilimumab 3 mg/kg intravenously over 90 minutes once every 3 weeks for 4 doses, beginning soon after delivery. She began breastfeeding 21 days after her 12 weeks of therapy was completed. At 30 weeks after treatment she was well, but no mention was made of the duration of breastfeeding or the health of her infant.[4]

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.
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.
4. Ross E, Robinson SE, Amato C et al. Therapeutic monoclonal antibodies in human breast milk: A case study. Melanoma Res. 2014;24:177-80. PubMed PMID: 24476799.

Substance Identification

Substance Name

Ipilimumab

CAS Registry Number

477202-00-9

Drug Class

Breast Feeding

Lactation

Antibodies, Monoclonal

Antineoplastic Agents

Biological Response Modifiers

Immunologic Adjuvants

Immune Checkpoint Inhibitors