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Alglucosidase Alfa

Revised: April 15, 2023.

CASRN: 420784-05-0

Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that a maternal dose of 20 mg/kg every 2 weeks produces low levels in milk. Alglucosidase alfa activity was detectable in breastmilk for only 24 hours after a dose in one woman. The investigators recommended withholding breastfeeding for 24 hours after each dose as a precaution until more data are obtained.[1]

Drug Levels

Maternal Levels. One 40-year-old woman with adult-onset Pompe disease received alglucosidase alfa during pregnancy and lactation in an intravenous dose of 20 mg/kg every 2 weeks. The alglucosidase activity in breastmilk before the injection was 3 nmol/hour.ml, Which was about 10% of what the authors had measured in the milk of an unaffected woman. Breastmilk activity peaked 2.5 hours after the end of the infusion at 245 nmol/h.mL which was 0.3% of the peak plasma value. Direct measurement of alglucosidase alfa in the breastmilk of the normal mother and the mother receiving the drug were consistent with these activity measurements. Alglucosidase alfa was undetectable (assay limit not stated) 24 hours after the end of the infusion.[1]

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

Effects in Breastfed Infants

An infant was born to a mother receiving alglucosidase alfa during pregnancy and lactation in an intravenous dose of 20 mg/kg every 2 weeks for adult-onset Pompe disease. At 3 and 77 days of age, the infant's serum had negligible anti-alglucosidase alfa antibodies. The infant was examined regularly up to 1 year of age and showed normal development, although the extent of breastfeeding during this time was not stated.[1]

Two infants were born to mothers who received alglucosidase alfa therapy for Pompe disease during pregnancy and lactation. The two infants breastfed for a combined total of 22 months. Regular follow-up indicated normal development of both infants and a lack of side effects.[2]

A woman with juvenile Pompe disease was treated with recombinant human alglucosidase alfa (Myozyme, Sanofi Genzyme) at a dose 20 mg/kg every 2 weeks beginning at 16 years of age. At age 21, she continued therapy throughout pregnancy and during breastfeeding, with the instruction to defer breastfeeding for 24 hours after the start of the infusion. The infant had normal development at 6 months of age.[3]

A woman with late-onset Pompe disease was treated with alglucosidase starting after delivery. The infant was breastfed, with the instruction not to breastfeed for 24 hours after each infusion. At 2 months postpartum, therapy was changed to avalglucosidase. At 8 months postpartum, the infant was developing normally.[4]

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

Alglucosidase Alfa

CAS Registry Number

420784-05-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Enzymes

Enzyme Replacement Therapy