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Agalsidase Alfa

Revised: August 15, 2023.

CASRN: 104138-64-9

Drug Levels and Effects

Summary of Use during Lactation

Agalsidase alfa is not approved for marketing in the United States by the U.S. Food and Drug Administration, but is available in other countries. Because it is a large protein molecule with a molecular weight of about 100,000, 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. Six infants who were breastfed for periods up to 12 months by mothers taking agalsidase alfa experienced no adverse effects associated with the drug.

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

Six patients with Fabry disease were treated with agalsidase alfa 0.2 mg/kg every 2 weeks during pregnancy and postpartum. One infant partially breastfed for 10 months had asthma at age 4 years and an infant who was partially breastfed for 5 months had recurrent urinary tract infections up to 2 years, but was normal at the age of 5 years. Three infants who were exclusively breastfed for 6 months and partially breastfed until 12 months and one partially breastfed for 12 months were normal. None of the adverse effects appear to have been associated with agalsidase alfa.[1]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Agalsidase Beta

References

1. Fernández P, Fernández SO, González JGM, et al. Enzyme replacement therapy in pregnant women with Fabry disease A case series. JIMD Rep 2019;45:77-81. PubMed PMID: 30406505.

Substance Identification

Substance Name

Agalsidase Alfa

CAS Registry Number

104138-64-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Enzymes

Enzyme Replacement Therapy

Alpha-Galactosidase