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NLM Citation: Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Velaglucerase alfa. [Updated 2018 Dec 3].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Velaglucerase alfa

Revised: December 3, 2018.

CASRN: 884604-91-5

Drug Levels and Effects

Summary of Use during Lactation

No information is available on the clinical use of velaglucerase during breastfeeding. Velalglucerase is a synthetic form of beta-glucocerebrosidase, which is a normal component of human milk. Studies with other forms of the enzyme have found very low levels of the enzyme in breastmilk. Absorption by the infant is unlikely because it is probably destroyed in the infant's gastrointestinal tract.[1][2] A limited amount of data support the safety of breastfeeding with alglucerase (the placenta-derived form of the enzyme) and imiglucerase (another biosynthetic form of the enzyme). An international panel of clinicians from 9 centers that treat Gaucher's disease reported that, breastfeeding complications were less frequent in mothers who were treated with alglucerase or imiglucerase postpartum than in untreated mothers with Gaucher's disease. Consider limiting the duration of breastfeeding to about 6 months to avoid excessive bone loss in the nursing mother.[2][3]

Drug Levels

Maternal Levels. One woman received 60 units/kg of alglucerase intravenously. Alglucerase appeared in breastmilk in levels above the baseline control values at 2, 6, 12, 24 and 48 hours postinfusion. Concentrations ranged between 69 and 187 ng/L above baseline.[4]

In one patient taking imiglucerase 60 units/kg every 2 weeks, the imiglucerase level in breastmilk was elevated above baseline at 1 hour afer the end of the infusion and was at baseline by 5 hours after the dose.[5]

A woman with type 1 Gaucher's disease was exclusively breastfeeding her infant postpartum re-initiated intravenous imiglucerase 30 units/kg over 2 hours every 2 weeks at 1 month postpartum. Milk beta-glucocerebrosidase activity was measured at the time of her first postpartum dose, milk. Before the infusion activity was 2 nanomoles/hour/mL. Milk levels were 3 and 4 nanomoles/hour/mL immediately after and 30 minutes after the infusion, respectively. These values were much lower than the level of 42 nanomoles/hour/mL measured in the milk of a control mother without Gaucher's disease.[6] *Infant Levels.* Relevant published information was not found as of the revision date.

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 .

Effects in Breastfed Infants

One woman received alglucerase 30 international units/kg intravenously every 2 weeks during pregnancy and lactation. Her breastfed infant reportedly grew and developed normally.[7]

A woman received imiglucerase 30 units/kg every 2 weeks during pregnancy and for 3 months while breastfeeding. The dose was then increased to 60 units/kg every 2 weeks because of disease progression, and she continued breastfeeding until the infant was 1 year old.[8]

A woman receiving long-term therapy with imiglucerase 60 units/kg intravenously every 2 weeks became pregnant twice during therapy and breastfed both infants (extent not stated). Both infants developed normally during the observation periods of 13 and 33 months.[5]

A woman with type 1 Gaucher's disease was exclusively breastfeeding her infant postpartum re-initiated intravenous imiglucerase 30 units/kg every 2 weeks beginning at 1 month postpartum. The infant was breastfed for about 9 months postpartum and was reportedly healthy when followed up to 3 years of age.[6]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Alglucerase, Imiglucerase, Taliglucerase Alfa

References

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Substance Identification

Substance Name

Velaglucerase alfa

CAS Registry Number

884604-91-5

Drug Class

Breast Feeding

Lactation

Enzymes

Enzyme Replacement Therapy