



Imiglucerase

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CASRN: 143003-46-7

Drug Levels and Effects

Summary of Use during Lactation

Imiglucerase is a synthetic form of beta-glucocerebrosidase, which is a normal component of human milk. After therapeutic use of imiglucerase, breastmilk levels are lower than those of normal mothers.[1] Additionally, absorption by the infant is unlikely because it is probably destroyed in the infant's gastrointestinal tract.[2,3] A limited amount of data support the safety of breastfeeding with imiglucerase. 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 imiglucerase or alglucerase (the placenta-derived form of the enzyme) 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.[3,4]

Drug Levels

Maternal Levels. A woman on long-term imiglucerase therapy for Gaucher's disease was monitored after her usual dose of 60 units/kg intravenously every 2 weeks. At 6 months postpartum, milk samples were obtained and measured for beta-glucocerebrosidase activity, using milk from 10 mothers with galactorrhea as controls. The highest enzyme activity in milk was 16 nanomoles/hour/mL at 1 hour after the end of the infusion. Enzymatic activity decreased to the preinfusion level (0.008 nanomoles/hour/mL) in the samples of breastmilk taken about 5 hours after the end of the infusion and remained low for all samples taken over the first 24 hours after the dose. Breastmilk beta-glucocerebrosidase activity of the control subjects ranged from 0.067 to 0.214 nanomoles/hour/mL.[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.[1]

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.

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

Effects in Breastfed Infants

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.[6]

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.[1]

A woman with Gaucher's disease received imiglucerase 1800 units (30 units/kg) every 2 weeks during pregnancy and postpartum. Her infant was breastfed (extent not stated) and was followed by a pediatrician who determined that development was normal over 2 years.[7]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Alglucerase, Taliglucerase Alfa

References

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Substance Identification

Substance Name

Imiglucerase

CAS Registry Number

143003-46-7

Drug Class

Breast Feeding

Lactation

Enzymes

Enzyme Replacement Therapy