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Imiglucerase

Revised: December 3, 2018.

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]

One woman received 60 units/kg of alglucerase intravenously. Alglucerase appeared in breastmilk in levels above the baseline control values at 12, 6, 12, 24 and 48 hours postinfusion. Concentrations ranged between 67 and 187 mg/L above baseline.[6]

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

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.[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.[9]

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