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Taliglucerase alfa

Revised: February 28, 2019.

CASRN: 37228-64-1

Drug Levels and Effects

Summary of Use during Lactation

No information is available on the clinical use of taliglucerase alfa during breastfeeding. Taliglucerase alfa is a biosynthetic synthetic enzyme closely related to beta-glucocerebrosidase, which is a normal component of human milk. Because it is a large protein molecule with a molecular weight of about 61,000, 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.[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. A woman with Gaucher disease received taliglucerase alfa 20 units/kg intravenously every 2 weeks during pregnancy and postpartum during breastfeeding. One month after delivery, breastmilk samples were collected before, immediately after, and 30 minutes after an infusion of the drug. Beta-glucocerebrosidase activity in breastmilk were: 3.9 nmol/hour/mL before the infusion, 7.1 nmol/hour/mL immediately after infusion, and 7.2 nmol/hour/mL 30 minutes after infusion. These values are lower than those found in the milk of mothers treated with other replacement enzymes. The woman breastfed her infant exclusively on demand through 10 months of age.[4]

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

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

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

References

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2. Zimran A, Morris E, Mengel E et al. The female Gaucher patient: the impact of enzyme replacement therapy around key reproductive events (menstruation, pregnancy and menopause). Blood Cells Molec Dis. 2009;43:264-88. PubMed PMID: 19502088.
3. Granovsky-Grisaru S, Belmatoug N, vom Dahl S. The management of pregnancy in Gaucher disease. Eur J Obstet Gynecol Reprod Biol. 2011;156:3-8. PubMed PMID: 21269752.
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Substance Identification

Substance Name

Taliglucerase alfa

CAS Registry Number

37228-64-1

Drug Class

Breast Feeding

Lactation

Enzymes

Enzyme Replacement Therapy