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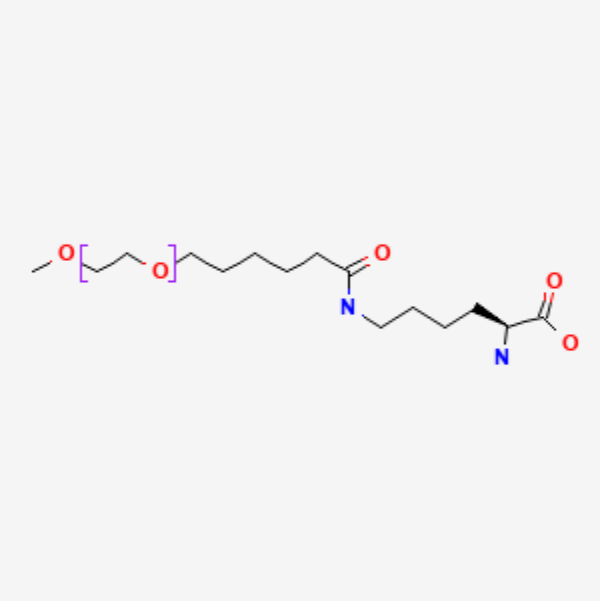
Pegvaliase

Revised: November 30, 2022.

CASRN: 1585984-95-7



Drug Levels and Effects

Summary of Use during Lactation

No information is available on the use of pegvaliase during breastfeeding, but amounts in milk appear to be trivial. Absorption of the drug by the infant from breastmilk is unlikely because it is a polypeptide that is probably destroyed in the infant's gastrointestinal tract. Polyethylene glycol is not excreted into breastmilk.[1] Pegvaliase may decrease the phenylalanine content of breastmilk. The manufacturer recommends monitoring blood phenylalanine concentrations in breastfeeding women treated with pegvaliase.

Drug Levels

Maternal Levels. A woman with phenylketonuria stopped her pegvaliase during pregnancy and for 7 months while breastfeeding her infant. After weaning, she restarted pegvaliase and pumped breastmilk samples for analysis while taking a dose of 20 mg daily. The activity of phenylalanine ammonia lyase (the active portion of pegvaliase) was equal to background levels found in blank breastmilk and TRIS buffer solution.[2] In her second pregnancy, pegvaliase was measured in breastmilk at four time points when she was receiving o, 80, 110 and 140 mg of pegvaliase weekly. No sample had any detectable pegvaliase activity.[3]

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

Effects in Breastfed Infants

A woman with phenylketonuria reinstituted pegvaliase therapy when her infant was 2 weeks old. She began with a dose of 10 mg per week on day 12 postpartum, then increased to 70 mg per week on day 27 postpartum, 140 mg per week on day 46 postpartum. The dosage was reduced to 80 mg weekly on day 55 postpartum, then increased to 110 mg weekly on day 97 postpartum, where it remained. She breastfed her infant breastfed twice daily and the infant gained weight normally and met developmental milestones. Mental development was average at 14 months of age.[3]

Effects on Lactation and Breastmilk

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

References

1. Clowse ME, Förger F, Hwang C, et al. Minimal to no transfer of certolizumab pegol into breast milk: Results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. Ann Rheum Dis. 2017;76:1890–6. PubMed PMID: 28814432.
2. Rohr F, Kritzer A, Harding CO, et al. Discontinuation of pegvaliase therapy during maternal PKU pregnancy and postnatal breastfeeding: A case report. Mol Genet Metab Rep. 2020;22:100555. PubMed PMID: 31956506.
3. Rohr F, Wessel A, Harding CO, et al. Reinstitution of pegvaliase therapy during lactation. Mol Genet Metab Rep. 2022;33:100938. PubMed PMID: 36420422.

Substance Identification

Substance Name

Pegvaliase

CAS Registry Number

1585984-95-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Enzymes

Lyases

Recombinant Proteins

Phenylalanine Ammonia Lyase,