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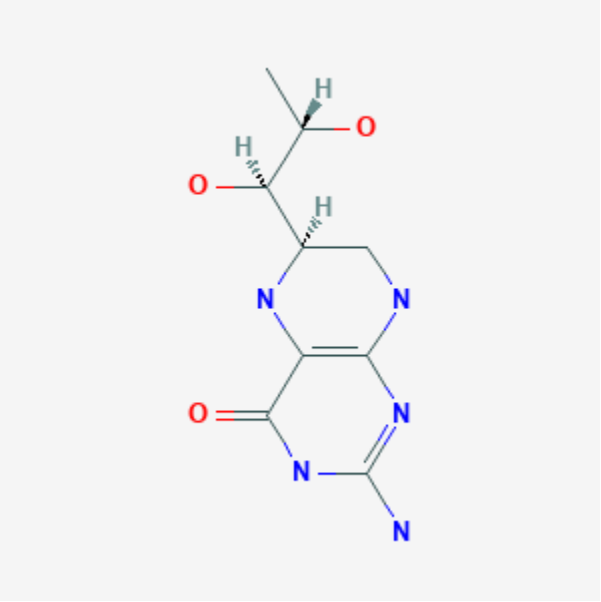
Sapropterin

Revised: May 11, 2020.

CASRN: 62989-33-7



Drug Levels and Effects

Summary of Use during Lactation

Sapropterin is a synthetic form of the naturally occurring enzyme cofactor tetrahydrobiopterin (BH4) and is used in the treatment of phenylketonuria. BH4 is found in normal human milk and is a cofactor in multiple reactions including serving as a catalyst to phenylalanine hydroxylase. In two postmarketing pregnancy registries of women taking sapropterin, a total of 16 women were identified as breastfeeding for a mean of 3.5 months. No lactation-related safety concerns were reported in infants of mothers nursing during maternal treatment with sapropterin. United States and European guidelines state that sapropterin dihydrochloride supplementation is not contraindicated as an adjunct to dietary therapy in breastfeeding women who are responsive to BH4.[1,2]

Drug Levels

Maternal Levels. Breastmilk was obtained from 10 women, colostrum from 9 and mature milk from 6. Colostrum levels of BH4 averaged about 100 nmol/L (241 mcg/L) and mature milk levels averaged about 500 nmol/L (1200 mcg/L). The difference between colostrum and mature milk was statistically significant.[3]

Three mothers who were taking sapropterin for phenylketonuria had breastmilk samples taken at times that were not reported. Their milk BH4 levels were greater than reported in normal human milk, but specific values were not reported.[4]

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

Effects in Breastfed Infants

A Japanese woman with phenylketonuria took sapropterin dihydrochloride 500 mg (10 mg/kg) daily during pregnancy and postpartum. She breastfed her infant (extent not stated) until 25 months of age. The infant had normal developmental milestones and normal growth at 31 months of age.[5]

Effects on Lactation and Breastmilk

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

References

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Substance Identification

Substance Name

Sapropterin

CAS Registry Number

62989-33-7

Drug Class

Breast Feeding

Lactation

Coenzymes