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C1 Esterase Inhibitor

Revised: August 15, 2023.

CASRN: 80295-38-1

Drug Levels and Effects

Summary of Use during Lactation

C1 esterase inhibitor [human] is a serine proteinase inhibitor derived from human plasma that is used in treating hereditary angioedema. Breastmilk levels of C1 esterase inhibitor have not been measured after exogenous administration in humans. Because of its large molecular weight, amounts in milk are expected to be small. Any C1 esterase inhibitor in breastmilk is probably destroyed in the infant's gastrointestinal tract and not absorbed, except perhaps in neonates. Various international consensus panels state that human plasma-derived C1 esterase inhibitor is considered to be the therapy of choice for both treatment and short- and long-term prophylaxis of maternal hereditary angioedema during lactation. Recombinant human C1 esterase inhibitor is a valid alternative.[1-4] A patient with Factor XII hereditary angioedema was also successfully treated with subcutaneous C1 esterase inhibitor during pregnancy and lactation.[5]

Drug Levels

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

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

Effects in Breastfed Infants

Three patients with hereditary angioedema received C1 esterase inhibitor concentrate on 12 occasions to relieve abdominal edematous episodes during breastfeeding. No adverse reactions were reported.[6]

In a case series spanning 12 years, 21 mothers with hereditary angioedema breastfed their infants for a median duration of 4.8 months (range 1 to 34 months) while receiving C1 esterase inhibitor concentrate as needed. No side effects occurred in the breastfed infants.[7]

A pregnant woman with severe hereditary angioedema required 500 IU of C1 inhibitor concentrate every 2 days to maintain her pregnancy. Postpartum, she received 500 IU on demand while breastfeeding. She used 88 vitals

during her 6-month breastfeeding (extent not stated) period. No side effects or viral transmission were reported and or virus anti-C1-INH antibodies were not detected.[8]

A woman with hereditary angioedema received C1 inhibitor concentrate 1000 units every week during pregnancy. Postpartum she used 500 units as needed. She and her breastfed infant were reportedly healthy.[9]

A woman with hereditary angioedema used subcutaneous C1 esterase inhibitor concentrate 1500 units prophylactically twice a week during pregnancy and postpartum. At 7 weeks postpartum she was able to decrease the frequency to once weekly for 7 weeks, but then increased the frequency to twice weekly until almost 10 months postpartum. During this time, she breastfed her infant although the extent and duration were not stated. There was no mention of any adverse effects in her infant.[10]

A 29-year-old woman with a long history of hereditary angioedema received subcutaneous C1-esterase therapy during pregnancy and postpartum in a dose of "2 x 3000 IU/week" (presumably 3000 IU twice weekly). She breastfed her infant, but the extent and duration of breastfeeding was not specified. The authors reported that the infant experienced no adverse reactions.[11]

Effects on Lactation and Breastmilk

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

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Substance Identification

Substance Name

C1 Esterase Inhibitor

CAS Registry Number

80295-38-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Complement C1 Inactivator Proteins