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Eculizumab

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CASRN: 219685-50-4

Drug Levels and Effects

Summary of Use during Lactation

Maternal dosages of eculizumab usually produce undetectable levels in breastmilk. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] No adverse effects attributable to eculizumab have been reported in infants who were breastfed during maternal therapy. Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[2]

Drug Levels

Maternal Levels. Two women began treatment with eculizumab for paroxysmal nocturnal hemoglobinuria during pregnancy and continued receiving the drug postpartum while breastfeeding their infants. Serum and breastmilk samples were obtained at 12 hours and 5 days after their last dose. Eculizumab was not detectable (assay limit not specified) in breastmilk despite therapeutic serum concentrations.[3]

A woman treated with eculizumab 900 mg twice weekly for paroxysmal nocturnal hemoglobinuria during pregnancy had her breastmilk tested for the presence of the drug. She received a dose one day after delivery. A milk sample one day later had detectable eculizumab, but in an amount less than 35 mg/L. Eight more breastmilk samples taken up to 12 days postpartum and 13 days after the postpartum dose had no detectable eculizumab.[4]

Twenty-five women were identified who were taking eculizumab for paroxysmal nocturnal hemoglobinuria during breastfeeding. Ten of the women receiving unstated dosages of the drug had a breastmilk sample tested for eculizumab, which was undetectable (<5 mg/L) in all samples.[5]

A woman with paroxysmal nocturnal hemoglobinuria was found to be pregnant at 20 weeks of gestation. She was treated with eculizumab 900 mg weekly starting at 30 weeks of gestation and then 1200 mg every 2 weeks beginning at 34 weeks of gestation. The drug was continued at this dosage throughout the pregnancy and for 3 months postpartum. The patient delivered at 36 weeks of gestation and eculizumab was undetectable (assay limit

not specified) in breastmilk at that time.[6] The time between the last dose and measurement of milk levels was not stated.

Three cases of Japanese women treated for paroxysmal nocturnal hemoglobinuria reportedly were given eculizumab during pregnancy and postpartum. The dosage was 900 mg every 2 weeks in two cases and unstated in the third. Eculizumab was undetectable (assay limit not specified) in breastmilk in all cases, apparently at the time of delivery.[7]

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

Effects in Breastfed Infants

Two women began treatment with eculizumab during pregnancy and continued receiving the drug postpartum while breastfeeding their infants. One infant had no complications up to 30 weeks of follow-up. The other infant developed neutropenia up to 12 weeks of age, but it was not attributed to eculizumab.[3]

A group of authors associated with the manufacturer of the drug reported that 25 patients had breastfed while taking eculizumab for paroxysmal nocturnal hemoglobinuria. Infant outcomes were not stated.[5]

One center reported a cohort of 14 women who received eculizumab for paroxysmal nocturnal hemoglobinuria during pregnancy. Ten of the infants were breastfed (extent not stated) with no reported complications.[8,9]

A mother with paroxysmal nocturnal hemoglobinuria became pregnant while on eculizumab and continued the drug during pregnancy and lactation. During the third trimester and immediately postpartum she was receiving 1200 mg weekly. One month postpartum, her dosage was decreased to 900 mg every 2 weeks. She continued to breastfeed her baby for six months (extent not stated). At 3 months and one year of age of age, the infant was developing normally for her age.[10,11]

Academic and manufacturer personnel analyzed the manufacturer's pharmacovigilance database. There were 31 reports of mothers breastfeeding their infants during eculizumab therapy, 20 patients with paroxysmal nocturnal hemoglobinuria and 11 patients with atypical hemolytic uremic syndrome. Neither dosages nor extent of breastfeeding were reported, and some of the cases might have been reported elsewhere previously. None of the breastfed infants had any adverse effects.[12]

One center reported their experience with women who received eculizumab for hemolytic-uremic syndrome. Four of the women became pregnant and subsequently breastfed their infants (extent and duration not stated). No long-term complications were seen in the infants.[13]

A woman with neuromyelitis optica spectrum disorder was receiving eculizumab, tacrolimus and prednisolone in unspecified dosages. Two years and 3 months after starting eculizumab, she conceived and delivered a healthy fullterm infant. At 6 months postpartum, the infant was reported to have no developmental problems.[14]

Effects on Lactation and Breastmilk

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

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Substance Identification

Substance Name

Eculizumab

CAS Registry Number

219685-50-4

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal

Dermatologic Agents