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Romiplostim

Revised: May 15, 2023.

CASRN: 267639-76-9

Drug Levels and Effects

Summary of Use during Lactation

Romiplostim was detected in low levels in the breastmilk of one woman and in much lower levels in the serum of her infant. The infant had mild thrombocytosis that persisted after breastfeeding discontinuation, but no other medical complications. Information from another mother-infant pair found no short-term adverse effects after maternal romiplostim. Until more data become available, romiplostim should be used with careful infant monitoring of infant blood parameters during breastfeeding, especially while nursing a newborn or preterm infant.

Drug Levels

Maternal Levels. A woman with systemic lupus erythematosus and history of thrombosis and immune thrombocytopenia received romiplostim during pregnancy and postpartum in a dose of 120 mcg (2 mcg/kg) per week. A semiquantitative analysis of her milk found levels of romiplostim-associated amino acid sequences in her milk that were much higher than those in control milk from other mothers not taking romiplostim. At steady-state, the milk level was higher 1 day after the dose than 7 days after the dose.[1]

Infant Levels. A woman with systemic lupus erythematosus and history of thrombosis and immune thrombocytopenia received romiplostim during pregnancy and postpartum in a dose of 120 mcg (2 mcg/kg) per week. Her infant was breastfed and at 56 days postpartum, her blood level of romiplostim-associated amino acid sequences was 13.5 times higher than the infant's blood level. The infant's blood level was about the same as the level in breastmilk.[1]

Effects in Breastfed Infants

A woman with chronic immune thrombocytopenic purpura had a low platelet count after delivery even after receiving 5 units of platelets on two consecutive days. She also received intravenous methylprednisolone 500 mg daily for 2 days and intravenous immune globulin 1 gram/kg with poor response. The patient was given romiplostim 2 mcg/kg and 90 mg of prednisone orally on the evening of postpartum day 2 at about 68 hours

postpartum. She received a second dose of 2 mcg/kg romiplostim on the third postpartum day. Her platelet count increased and she was discharged on postpartum day 5. The patient elected to breastfeed her infant (extent not stated). No adverse effects were noted in the infant during the hospitalization.[2]

A woman with systemic lupus erythematosus and history of thrombosis and immune thrombocytopenia received romiplostim during pregnancy and postpartum in a dose of 120 mcg (2 mcg/kg) per week. On the day of delivery, the breastfed (extent not stated) neonate's platelet count was normal. Breastfeeding was initiated after birth. On day 9 of life, thrombocytosis was first noted. The peak platelet count occurred on day 22 of life. The mother discontinued breastfeeding at about 11 weeks postpartum because of the thrombocytosis and the presence of rare immature cells on the infant's peripheral blood smear, but with normal flow cytometry. Two weeks after stopping breastfeeding, no immature cells were identified and the platelet count improved but was still elevated. Mild thrombocytosis was seen up to 11 months of age. The authors felt that the persistent mild thrombocytosis after breastfeeding cessation indicated that romiplostim was not the sole cause of thrombocytosis. The infant had no other complications up to 22 months after delivery.[1]

Effects on Lactation and Breastmilk

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

References

1. Labrecque AA, Roy S, Young D, et al. Romiplostim drug presence in pregnancy and lactation. Blood. 2023;141:2537–40. PubMed PMID: 36848631.
2. Patras A, Figueroa R, Singh AP, et al. Romiplostim for management of refractory immune thrombocytopenic purpura in the immediate postpartum period. BMJ Case Rep. 2020;13:e234335.

Substance Identification

Substance Name

Romiplostim

CAS Registry Number

267639-76-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Recombinant Fusion Proteins

Thrombopoietin