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Ocrelizumab

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CASRN: 637334-45-3

Drug Levels and Effects

Summary of Use during Lactation

Amounts of ocrelizumab in milk are low and it is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] Many infants have been exposed to ocrelizumab during breastfeeding, with normal growth and no evidence of severe or persistent harm. Ocrelizumab appears to be acceptable to use during breastfeeding and breastfeeding can resume after the injection. Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[2]

Drug Levels

Maternal Levels. An international, multicenter study of patients with multiple sclerosis or neuromyelitis optica spectrum disorder collected breastmilk samples from 33 women who were receiving ocrelizumab. Milk samples were collected at a mean of 2.6 months (range 0.1–36) postpartum. The women received 300 mg once (n = 4) or twice (n = 10) or 600 mg (n = 16) and milk samples were collected before and up to 90 days after the dose. Where measurable (n = 16 samples), the peak concentration in milk usually occurred between 1 and 7 days after the dose. Milk concentrations were virtually undetectable at 90 days after a dose. For 4 women who received a single 300 mg dose, the average milk concentration was 0.08 mg/L and the peak was 0.4 mg/L. For 10 women who receive a single 600 mg dose, the average milk concentration was 0.1 mg/L and the peak was 0.3 mg/L. For 16 women who received two 300 mg doses, the average milk concentration was 0.08 mg/L and the peak was 0.2 mg/L. Based on the average milk levels, infants would receive a dose of 0.01 mg/kg daily.[3]

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

Effects in Breastfed Infants

A summary of pregnancies that occurred up to March 27, 2020, in clinical trials and postmarketing surveillance found 6 infants who had been breastfed during maternal ocrelizumab therapy for multiple sclerosis. Five infants were exposed to the drug in breastmilk, but no other data were available. One infant was exposed via breastmilk alone and had a slight decrease in B cells at 1 month of age, which returned to normal after 1 week. Another

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infant who was exposed during pregnancy and via breastmilk had excessive vomiting and swelling, but it was thought to be a potential dairy allergy.[4]

A retrospective cohort study from the German Multiple Sclerosis and Pregnancy Registry database identified 2 mothers who received ocrelizumab during breastfeeding. In one, the dose was 300 mg on day 20 postpartum and she nursed for 2.7 months after the dose. The second received 600 mg on day 194 postpartum and she nursed for 2.1 months after the dose. Blood counts were normal at well-baby visits at 59 and 39 days, respectively, after the dose and no abnormal infections had occurred. Another woman received rituximab 250 mg on day 55 postpartum and ocrelizumab 300 mg on day 333 postpartum. She breastfed for 22.9 months after the rituximab dose. Her infant had normal blood counts at 45 and 213 days after the rituximab dose, but had conjunctivitis and otitis media during this time.[5] Ocrelizumab exposure in breastmilk only had no effect on the B-cell count of one infant.[6] It is possible that these infants were include in the postmarketing surveillance above.

A retrospective study identified 4 patients with multiple sclerosis who received ocrelizumab 600 mg while breastfeeding (extent not stated). No adverse effects were reported in the infants.[7]

A multicenter study of women who were receiving either ocrelizumab (n = 30) or rituximab (n = 15) for multiple sclerosis or neuromyelitis optica spectrum disorder followed their infants. Forty-three women breastfed their infants (n = 27 exclusively, n = 16 partially) for a median of 6.4 months (range 0.3 to 11.7). In the first 12 months of life, all infants grew and developed normally compared to WHO standards and a group of infants who were not breastfed. Beyond minor infections common to infancy, no unexpectedly severe or frequent infections arose. Four infants between the ages of 2.1 and 6.2 months who were breastfed after maternal ocrelizumab or rituximab had IgG and CD19 levels within the normal range.[3]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Multiple Sclerosis) Glatiramer, Immune Globulin, Interferon beta, Methylprednisolone, Peginterferon beta

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Substance Identification

Substance Name

Ocrelizumab

CAS Registry Number

637334-45-3

Drug Class

Breast Feeding

Lactation

Milk, Human

Biological Response Modifiers

Immunologic Adjuvants

Antibodies, Monoclonal