

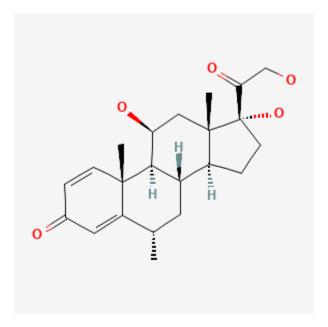
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Methylprednisolone

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CASRN: 83-43-2



Drug Levels and Effects

Summary of Use during Lactation

Amounts of methylprednisolone in breastmilk are very low and no adverse reactions in breastfed infants have been reported, even with intravenous doses of 1 gram. With maternal intravenous doses of 1 gram, fully breastfed infants would receive doses less than their daily cortisol output, and much less than the therapeutic dose used in neonates.[1,2] Accumulation of the drug does not occur in breastmilk with consecutive daily doses of 1 gram. Avoiding breastfeeding during the infusion and for as little as 2 hours after a 1 gram intravenous dose markedly reduces infant exposure. Smaller oral doses and local injections, such as for tendinitis, require no special precautions. Medium to large doses of corticosteroids given systemically or injected into joints or the breast have been reported to cause temporary reduction of lactation.

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Drug Levels

Maternal Levels. In one woman taking 6 mg daily of methylprednisolone by mouth, 2 peak milk levels occurred: one at 2 hours after the dose and another 8 hours after the dose. Peaks were about 7 mcg/L, while levels fell to about 2.5 mcg/L 6 hours after the dose and to about 1 mcg/L 10 hours after the dose.[3]

A woman with multiple sclerosis had a relapse in the first 3 months postpartum. She was given intravenous methylprednisolone 1 gram daily for 3 days. Milk samples were obtained after one of the doses. The breastmilk methylprednisolone was 3 mg/L immediately after the dose and 1.2 mg/L at 4 hours after the dose. The authors estimated that an infant who nurses at 4 hours after a dose will ingest 0.168 mg of methylprednisolone which is equivalent of 0.84 mg of cortisol or 42% of the daily output. An infant who nurses starting at 8 hours after a dose will ingest 0.048 mg of methylprednisolone which is equivalent to 12% of daily cortisol production. The authors did not specify their method of calculating these values.[4]

A woman with multiple sclerosis who was 5 months postpartum received 1 gram of methylprednisolone infused intravenously over 2 hours on 3 successive days. She provided milk samples at 0, 1, 2, 4, 8 and 12 hours after each dose. Breastmilk levels at 0 and 12 hours were not quantifiable (<0.06 mg/L). Peak levels occurred at 1 hour after the end of the infusion and averaged 5.3 mg/L (range 5.1 to 5.6 mg/L). By 4 hours after the dose, milk levels averaged 1.1 mg/L (range 1.0 to 1.6 mg/L) and by 8 hours, milk levels averaged 0.27 mg/L (range 0.2 to 0.37 mg/L). The authors calculated that a fully breastfed infant would have received an average of 0.19 mg/kg daily (range 0.16 to 0.21 mg/kg daily) of methylprednisolone, which is less than the lowest recommended therapeutic dose for infants. Withholding nursing for 2 to 4 hours after a dose would reduce the dose substantially.[5]

A woman who was nursing a 9-month-old infant was given intravenous methylprednisolone 1 gram daily for 3 days to treat multiple sclerosis. Cortisol milk levels were measured in breastmilk because of a lack of a methylprednisolone assay. The milk cortisol concentration was 306 mcg/L at the fourth hour after the last dose, which the authors state is approximately equal to the endogenous production of cortisol in an infant (note that normal breastmilk cortisol is less than 20 mcg/L). The authors considered that waiting 4 hours after a 1 gram dose of methylprednisolone before resuming breastfeeding to be adequate.[6]

Sixteen nursing mothers with multiple sclerosis received 1 gram of methylprednisolone intravenously over 1 hour, either monthly (n = 7) or over 3 consecutive days (n = 9).[7] Breastmilk samples were taken at 1, 2 4, 8 and 12 hours after each dose, and 2 women receiving 3 doses also provided milk samples prior to their doses. Peak milk methylprednisolone concentrations occurred 1 hour after the end of the infusion in all women and averaged 1.24 mg/L (range 0.55 to 2.1 mg/L). Subsequent average milk levels were 0.76 mg/L, 0.29 mg/L, 0.04 mg/L and 0.01 mg/L at 2, 4, 8 and 12 hours after the infusion, respectively. The average daily dosage over the 13 hours from the start of the infusion to 12 hours after the infusion was 0.047 mg/kg. No accumulation of the drug occurred in breastmilk of the mothers receiving 3 consecutive days of therapy.[7]

Twelve women with postpartum relapses of multiple sclerosis were given 1-hour infusions of methylprednisolone 1 gram daily for 3 to 5 days. Maternal blood and milk samples were obtained before and 0.5 hours after the start of the infusion, at the end of the infusion, and 1, 2, 4, 8, 12, and 24 hours after the end of the infusion. Milk methylprednisolone levels averaged 1, 2.09, 1.9, 1.17, 0.59, and 0.04 mg/L through 8 hours, respectively. Milk levels were below the quantification limit (<0.026 mg/L) before the infusion and at 12 and 24 hours after the infusion. The average milk level over 24 hours was 0.46 mg/L which resulted in an average infant dosage of 0.0695 mg/kg daily and a weight-adjusted relative infant dosage of 0.5%.[8]

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

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Effects in Breastfed Infants

None reported with methylprednisolone or any other corticosteroid. Three infants were breastfed from birth during maternal use of methylprednisolone 6 to 8 mg daily with no reported adverse effects up to 3 months.[3,9] In one of the papers, 2 infants had normal blood cell counts, no increase in infections and above average growth rates.[9]

Sixteen nursing mothers with multiple sclerosis received 1 gram of methylprednisolone intravenously over 1 hour, either monthly (n = 7) or over 3 consecutive days (n = 9). Infants did not breastfeed for 4 hours after the dose. No adverse effects were observed in infants during 3 to 12 months of follow-up.[7]

A woman with rheumatoid arthritis was treated during pregnancy with methylprednisolone 8 to 16 mg daily. After delivery, she was maintained on methylprednisolone 8 mg daily plus corticosteroid (not specified) injections into her metacarpal joints while breastfeeding (extent not stated) her infant. At 9 months of age, the baby had normal growth and psychomotor development, with no clinical nor laboratory alterations. The baby received routine vaccinations with no adverse effects. [10]

Twelve infants of mothers receiving methylprednisolone 1 gram intravenously over 1 hour for 3 or 5 days were breastfed by their mothers except for the first 2 hours after the infusion. The infants averaged 8 months of age (range 1 to 16 months). The infants were normal in weight and height and had reached their milestones at the time of the study. No adverse effects were seen in the infants during a 6 to 24 month follow-up period.[8]

Effects on Lactation and Breastmilk

A patient who was 6 weeks postpartum and predominantly breastfeeding her infant received 24 mg of depot methylprednisolone plus 15 mg of lidocaine intralesionally for tenosynovitis of the wrist. Thirty hours after the injection, lactation ceased. Her breasts were soft and not engorged at that time. Thirty-six hours later, lactation resumed slowly, reaching normal milk production 24 hours later. The author hypothesized that the suppression might have occurred because the injection was in a highly mobile joint, which might have caused rapid release of the corticosteroid. Medium to large doses of corticosteroids given systemically or injected into joints or the breast have been reported to cause temporary reduction of lactation.[11-15]

A study of 46 women who delivered an infant before 34 weeks of gestation found that a course of another corticosteroid (betamethasone, 2 intramuscular injections of 11.4 mg of betamethasone 24 hours apart) given between 3 and 9 days before delivery resulted in delayed lactogenesis II and lower average milk volumes during the 10 days after delivery. Milk volume was not affected if the infant was delivered less than 3 days or more than 10 days after the mother received the corticosteroid.[16] An equivalent dosage regimen of methylprednisolone might have the same effect.

A study of 87 pregnant women found that betamethasone given as above during pregnancy caused a premature stimulation of lactose secretion during pregnancy. Although the increase was statistically significant, the clinical importance appears to be minimal.[17] An equivalent dosage regimen of methylprednisolone might have the same effect.

Sixteen nursing mothers with multiple sclerosis received 1 gram of methylprednisolone intravenously over 1 hour, either monthly (n = 7) or over 3 consecutive days (n = 9). None of the mothers reported a decrease in their milk supply.[12]

Alternate Drugs to Consider

Prednisolone, Prednisone

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Substance Identification

Substance Name

Methylprednisolone

Methylprednisolone 5

CAS Registry Number

83-43-2

Drug Class

Breast Feeding

Lactation

Milk, Human

Corticosteroids, Systemic

Glucocorticoids

Anti-Inflammatory Agents