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Methylprednisolone

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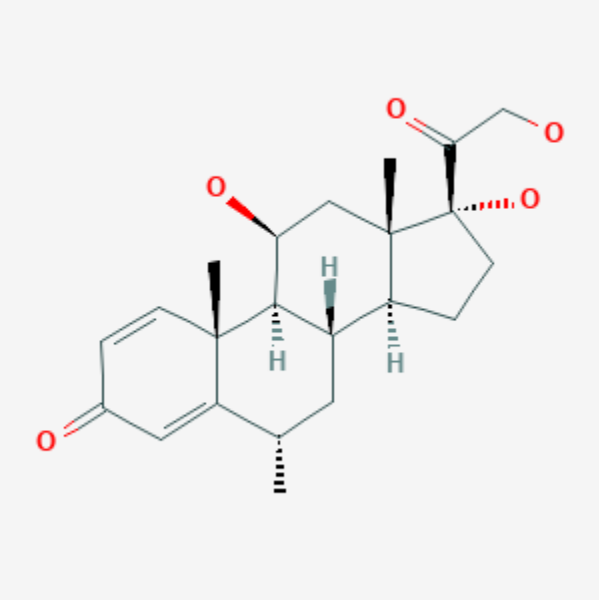
CASRN: 83-43-2



Drug Levels and Effects

Summary of Use during Lactation

Amounts of methylprednisolone in breastmilk are very low. No adverse effect have been reported in breastfed infants with maternal use of any corticosteroid during breastfeeding. With maternal intravenous doses of methylprednisolone 1 gram, fully breastfed infants would receive doses less than their daily cortisol output, and much less than a therapeutic dose on the day of infusion; accumulation of the drug does not occur in breastmilk with 3 consecutive daily doses. Avoiding breastfeeding during the infusion for as little as 2 hours after a 1 gram intravenous dose would markedly reduce infant exposure. Breastfeeding abstinence for 2 to 4 hours would further reduce the infant dose. Local injections, such as for tendinitis, would not be expected to cause any adverse effects in breastfed infants, but might occasionally cause temporary loss of milk supply.

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.[1]

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.[2]

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.[3]

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.[4]

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).[5] Breastmilk samples were taken at 1, 2 4, 8 and 12 hours after the each dose of their therapy, and 2 women receiving 3 doses also provided milk samples prior to their doses. Peak methylprednisolone concentrations occurred at 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, which is much lower than the methylprednisolone dosages of 1.6 to 30 mg/kg daily given to neonates safely.[6,7] The daily dosage that a fully breastfed infant would receive in breastmilk is lower than the average production of cortisol in infants and no accumulation of the drug occurred in breastmilk in the mothers receiving 3 consecutive days of therapy.[5] A subsequent abstract from the same authors reported 21 patients receiving methylprednisolone pulse therapy (dose not stated), but it is not clear if this includes the previous 16 patients. Milk levels in this study were somewhat higher, but the overall estimated daily infant dose was still quite low at 0.099 mg/kg.[8]

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

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.[1,9]

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.[10]

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.[11] Large doses of triamcinolone injected into the shoulder and into the wrist have also been reported to cause temporary drop or cessation of lactation.[12,13]

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.[13] 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.[14] 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.[10]

Alternate Drugs to Consider

Prednisolone, Prednisone

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Substance Identification

Substance Name

Methylprednisolone

CAS Registry Number

83-43-2

Drug Class

Breast Feeding

Lactation

Corticosteroids, Systemic

Glucocorticoids

Anti-Inflammatory Agents