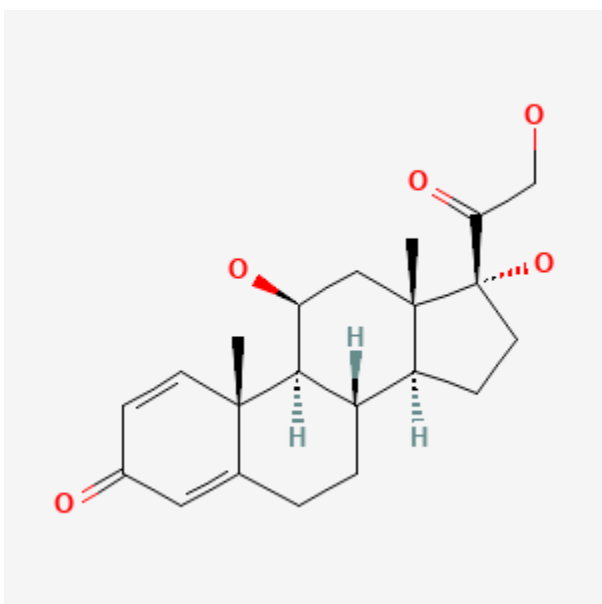




## Prednisolone

Revised: April 15, 2024.

CASRN: 50-24-8



## Drug Levels and Effects

### Summary of Use during Lactation

Amounts of prednisolone in breastmilk are very low. No adverse effect have been reported in breastfed infants with maternal use of any corticosteroid during breastfeeding. Although it is often recommended to avoid breastfeeding for 4 hours after a dose this maneuver is not necessary because prednisolone milk levels are very low. Medium to large doses of corticosteroids given systemically or injected into joints or the breast have been reported to cause temporary reduction of lactation.

Because absorption from the eye is limited, ophthalmic prednisolone would not be expected to cause any adverse effects in breastfed infants. To substantially diminish the amount of drug that reaches the breastmilk

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after using eye drops, place pressure over the tear duct by the corner of the eye for 1 minute or more, then remove the excess solution with an absorbent tissue.

## Drug Levels

*Maternal Levels.* Seven women were given 5 mg of radiolabeled prednisolone orally. A total of 0.14% of the total radioactivity was recovered from breastmilk over the next 48 to 61 hours.[1]

After oral prednisolone, levels of 23 to 40 mcg/L occurred with doses of 10 to 20 mg in 3 women, while peak levels of 106 and 137 mcg/L occurred after doses of 30 and 45 mg, respectively and a peak prednisolone level of 317 mcg/L occurred after a dose of 80 mg. The ratio of the peak milk to peak plasma prednisolone levels were about 0.1 with doses of 20 mg or less while it was 0.2 with doses of 30 mg or more. The ratios of the areas under the curve reached 0.2 only with an 80 mg dose. The higher ratios with higher doses is thought to be due to saturation of serum protein binding sites. Peak milk prednisolone levels occur about 1 hour after an oral dose of prednisolone and dropped with a half-life similar to the serum half-life. The authors estimated that a breastfed infant would receive less than 0.1% of the mother's total dosage of prednisolone; however, using the higher accepted milk intake value (150 mL/kg daily), this value would be less than 0.015% of the mother's dose.[2]

Three women were given 50 mg of prednisolone sodium phosphate intravenously. Thirty minutes after injection, milk prednisolone concentrations varied from about 200 to 400 mcg/L and dropped with a half-life slightly faster than the 2.5 hour half-life in serum. The authors estimated that a nursing infant would receive an average 0.074% of the total dose administered to the mother.[3]

An unpublished observation by the Berlin Teratogen Information Service found that 1 hour after parenteral administration of a single dose of 110 mg of prednisolone to a nursing mother, the milk level of prednisolone was 760 mcg/L. Four hours later it was 260 mcg/L, and about 9 hours after administration the level was 60 mcg/L. Following an intravenous injection of 1 gram of prednisolone, a nine-fold higher value was measured in the milk, reflecting the nine-fold higher dosage. Twenty-four hours after administration, it could no longer be detected in the milk. With the 1 gram dose, the infant received an estimated dose of 0.2 mg/kg of prednisolone with the first breast feed an hour after the injection. Over 24 hours, the dose was 0.32 mg/kg, which is about a sixth of a therapeutic child's dosage of 2 mg/kg daily. The authors concluded that there is no risk for the infant from the usual short-term high-dose maternal prednisolone treatment, even when breastfed right after the injection.[4]

Two women taking oral prednisone provided milk by complete breast emptying using a breast pump every 2 to 3 hours over one dosage interval. One subject was taking a dose of 2 mg every 12 hours and the other was taking 15 mg every 24 hours. The respective infant weight-adjusted dosages were 0.58% and 0.35% of the maternal dose for prednisone and 0.18% and 0.09% for prednisolone. Drug concentrations in milk were undetectable (<4 mcg/L) after 12 hours for prednisone and 6 hours for prednisolone.[5]

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

## Effects in Breastfed Infants

None reported with prednisolone or any other corticosteroid. In a prospective follow-up study, 6 nursing mothers reported taking prednisone (dosage unspecified) with no adverse infant effects.[6] There are several reports of mothers breastfeeding during long-term use of corticosteroids with no adverse infant effects: prednisone 10 mg daily (2 infants) and prednisolone 5 to 7.5 mg daily (14 infants).[7-9]

A woman who was nursing (extent not stated) her newborn infant was treated for pemphigus with oral prednisolone 25 mg daily, with the dosage increased over 2 weeks to 60 mg daily. She was also taking cetirizine 10 mg daily and topical betamethasone 0.1% twice daily to the lesions. Because of a poor response, the

betamethasone was changed to clobetasol propionate ointment 0.05%. She continued breastfeeding throughout treatment and her infant was developing normally at 8 weeks of age and beyond.[10]

A woman with pemphigoid gestationis was treated with prednisolone in a dosage tapering from 0.7 mg/kg daily to 1 mg daily during breastfeeding. She also received courses of intravenous immune globulin 2 grams/kg over 3 days at 4, 9 and 13 weeks postpartum. She breastfed her infant (extent not stated) for 3 months with no problems noted.[11]

Two mothers with systemic lupus erythematosus were reported who took prednisolone 30 or 40 mg daily during pregnancy and lactation as well as tacrolimus 3 mg daily. Three years after birth, both children were healthy. The durations of lactation were not stated.[12]

A woman with rheumatoid arthritis refractory to etanercept took sarilumab 200 mg every two weeks during pregnancy until 37 weeks of gestation. She was also taking prednisolone 10 mg and tacrolimus 3 mg daily. She delivered a healthy infant at 38 weeks of gestation and breastfed her infant. Prednisolone was continued postpartum, tacrolimus was restarted at 7 days postpartum, and sarilumab was restarted at 28 days postpartum. The mother continued to breastfeed until 6 months postpartum. The infant was vaccinated with multiple live vaccines after reaching six months old, including the Bacille-Calmette-Guerin vaccine, with no adverse effects. [13]

## Effects on Lactation and Breastmilk

Published information on the effects of prednisolone on serum prolactin or on lactation in nursing mothers was not found as of the revision date. Medium to large doses of corticosteroids given systemically or injected into joints or the breast have been reported to cause temporary reduction of lactation.[14-18]

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.[19] An equivalent dosage regimen of prednisolone 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.[20] An equivalent dosage regimen of prednisolone might have the same effect.

## Alternate Drugs to Consider

Methylprednisolone, Prednisone

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## Substance Identification

### Substance Name

Prednisolone

### CAS Registry Number

50-24-8

## **Drug Class**

Breast Feeding

Lactation

Milk, Human

Corticosteroids, Systemic

Corticosteroids, Ophthalmic

Glucocorticoids

Anti-Inflammatory Agents