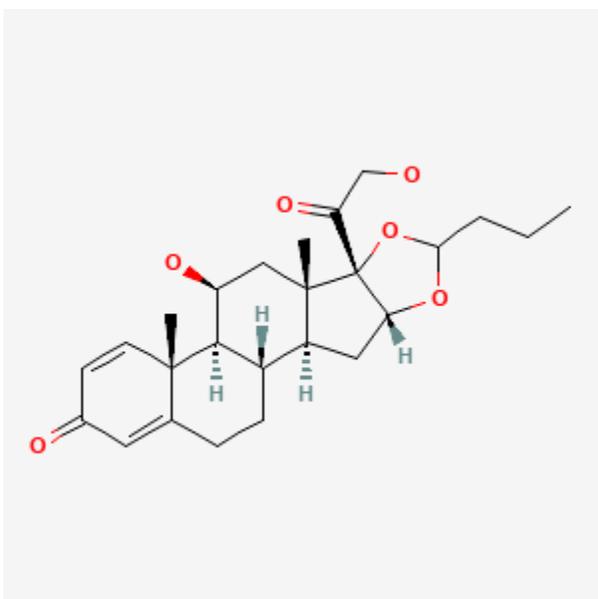




Budesonide

Revised: April 15, 2024.

CASRN: 51333-22-3



Drug Levels and Effects

Summary of Use during Lactation

The amounts of inhaled budesonide excreted into breastmilk are minute and infant exposure is negligible. When taken by mouth, budesonide is only about 9% bioavailable; bioavailability in the infant is likely to be similarly low for any budesonide that enters the breastmilk. Expert opinion considers inhaled, nasal, oral and rectal corticosteroids acceptable to use during breastfeeding.[1-3]

Drug Levels

Maternal Levels. The manufacturer reports that the maximum budesonide plasma concentration following a 9 mg daily dose in both single- and repeated-dose pharmacokinetic studies of oral budesonide ranges from 2.15 to

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4.31 mcg/L, which is 10 times higher than with inhaled budesonide. With rectal budesonide, maternal serum levels are about 0.4 mcg/L. Inhaled budesonide results in a relative infant dose of 0.3%, so the oral dose could provide an oral weight-adjusted dose of 3% to a breastfed infant. However, since the drug is only about 9% absorbed orally, the infant's systemic RID after maternal oral use would be about 0.27%. The RID after rectal budesonide would be about 0.025%.

Eight women with asthma were using inhaled budesonide 200 mcg (n = 4) or 400 mcg twice daily (n = 4) by Pulmicort Turbinaler. Peak milk levels of budesonide of 168 ng/L and 335 ng/L occurred at 32 and 43 minutes after inhalation with the 200 mcg and 400 mcg doses, respectively. Average infant doses were estimated to be 6.8 and 14.2 ng/kg daily for the 200 mcg and 400 mcg dosages. A fully breastfed infant would receive a maximum of 0.3% of the weight-adjusted maternal dosage, assuming 100% oral bioavailability from breastmilk.[4]

Infant Levels. Four infants whose mothers were taking budesonide 200 mcg (n = 2) or 400 mcg (n = 2) twice daily by Pulmicort Turbinaler. The infants had serum samples taken 1.5 hours (range 0.7 to 2 hours) after the first breastfeeding after drug administration and 2.3 hours (range 2.1 to 2.6 hours) after maternal drug inhalation. All had undetectable (<8.6 to 17.2 ng/L) serum budesonide concentrations.[4]

Effects in Breastfed Infants

None reported with any corticosteroid.

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Inhalation) [Beclomethasone](#)

References

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3. McConnell RA, Mahadevan U. Pregnancy and the patient with inflammatory bowel disease: Fertility, treatment, delivery, and complications. *Gastroenterol Clin North Am* 2016;45:285-301. PubMed PMID: 27261899.
4. Fält A, Bengtsson T, Kennedy BM, et al. Exposure of infants to budesonide through breast milk of asthmatic mothers. *J Allergy Clin Immunol* 2007;120:798-802. PubMed PMID: 17825891.

Substance Identification

Substance Name

Budesonide

CAS Registry Number

51333-22-3

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Asthmatic Agents

Corticosteroids, Inhaled

Anti-allergic Agents

Corticosteroids, Systemic

Glucocorticoids

Anti-Inflammatory Agents