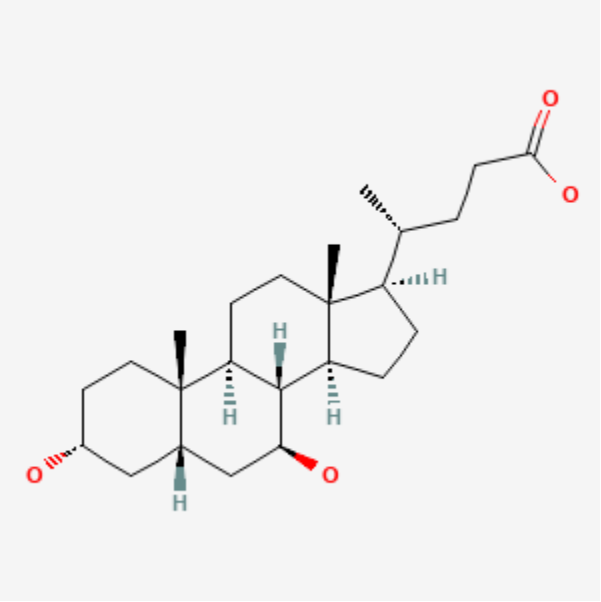
U.S. National Library of Medicine
National Center for Biotechnology Information

NLM Citation: Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Ursodiol. [Updated 2023 Oct 15].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Ursodiol

Revised: October 15, 2023.

CASRN: 128-13-2



Drug Levels and Effects

Summary of Use during Lactation

Ursodiol is naturally present in human milk. Because of the low levels of ursodiol (ursodeoxycholic acid) in breastmilk after exogenous administration, amounts ingested by the infant are small and are not expected to cause any adverse effects in breastfed infants.[1,2] Ursodiol has been given directly to newborns to safely and successfully treat prolonged neonatal jaundice.[3] No special precautions are required.

Drug Levels

Maternal Levels. A woman received oral ursodiol 750 mg daily throughout pregnancy for primary biliary cirrhosis. She continued ursodiol postpartum and ursodiol was undetectable in her breastmilk by HPLC assay. Details of milk collection and assay limits were not reported.[4]

Seven mothers with intrahepatic cholestasis of pregnancy were given oral ursodiol 14 mg/kg daily beginning an average of 14 days prior to delivery and continuing postpartum. Colostrum samples taken in the first 72 hours postpartum contained an average of 118 mcg/L. The mothers treated with ursodiol had levels of bile acids in colostrum that were much less elevated than 9 untreated control women with cholestasis of pregnancy.[5]

A woman with primary biliary cirrhosis developed severe pruritus and elevated serum bile acids 3 weeks postpartum. Ursodiol was started at a dose of 500 mg (7.5 mg/kg) daily increased to 1500 mg (25 mg/kg) daily over the next 8 weeks. Total bile acids in breastmilk increased from 0.5 micromole/L to 1 micromole/L after 8 weeks of therapy; after 16 weeks, total bile acids in milk were 0.6 micromole/L. Ursodiol milk levels were undetectable before drug initiation, 63 mcg/L at an ursodiol dose of 500 mg daily after 2 weeks, 118 mcg/L with a dose of 1 gram daily after 4 weeks, 79 mcg/L with a dose of 1.5 grams daily after 11 weeks, and 196 mcg/L with a dose of 1.5 grams daily after 19 weeks.[6] This patient was included in the following study: Twenty patients were taking ursodiol for cholestasis in daily dosages of 500 to 1500 mg or 13 to 15 mg/kg, depending on the condition. Milk samples were obtained on day 3 postpartum from the patients as well as 4 normal volunteers who were not taking ursodiol. No difference in the total bile acid concentration in breastmilk was found between the two groups of patients (3.2 micromolar), although the proportion of ursodiol was higher in the milk of mothers taking the drug (1.5 vs 21.5%). The authors estimated that a breastfed neonate would have a daily intake of 27 mcg of ursodiol, which would represent 0.0005% of the total newborn bile acid pool.[2]

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

Effects in Breastfed Infants

One breastfed (extent not stated) infant developed normally over the first 6 months of life during maternal ursodiol therapy of 750 to 1000 mg daily.[4]

Seven women who were taking ursodiol 14 mg/kg daily near term and postpartum. They reported no adverse reactions in their breastfed infants during the early postpartum period.[5]

A mother receiving oral ursodiol 250 mg 3 times daily for primary biliary cirrhosis reportedly breastfed her infant normally, although the extent and duration of breastfeeding was not stated.[7]

A woman with primary biliary cirrhosis developed severe pruritus and elevated serum bile acids 3 weeks postpartum. Ursodiol was started at a dose of 500 mg (7.5 mg/kg) daily, increasing to 1500 mg (25 mg/kg) daily over the next 8 weeks. Psychomotor development of her breastfed (extent not stated) infant was normal, and no apparent side effects were observed in the infant.[6]

A retrospective review of the medical records of pregnant patients at a hospital in Ankara, Turkey who had a diagnosis of primary biliary cirrhosis found 8 patients who took ursodiol postpartum in doses of 13–15 mg/kg daily. “Most” of the patients breastfed their infants (extent not stated). No infant side effects were reported.[8]

A woman was breastfeeding her 8-day-old preterm infant 10 times daily for about 15 minutes each time. The infant was born by cesarean section at 34 weeks of gestation with a weight of 3600 grams. She was diagnosed with cholestasis, type 1 diabetes, and hypothyroidism. She was treated with ursodiol 500 mg daily, insulin levemir and aspart, and levothyroxine. She was also taking cefuroxime, flurbiprofen, a combination of acetaminophen, propyphenazone, and caffeine. The mother took the ursodiol for a total of 12 days, cefuroxime

and the analgesic combination for 10 days and flurbiprofen for 15 days. No adverse effects were noticed during the period of ursodiol treatment.[9]

Twenty nursing mothers were taking ursodiol for cholestasis in daily dosages of 500 to 1500 mg or 13 to 15 mg/kg, depending on the condition. Ursodiol was discontinued 3 days postpartum. No apparent side effects were observed in any newborn infant based on standard clinical examination during early postnatal period, and no deterioration in postnatal development was observed during routine 1-year follow-up on routine pediatric examinations.[2]

Effects on Lactation and Breastmilk

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

References

1. de Vries E, Beuers U. Ursodeoxycholic acid in pregnancy? J Hepatol 2019;71:1237-45. PubMed PMID: 31479696.
2. Šimják P, Petr T, Kaslová B, et al. Ursodeoxycholic acid use in lactating female patients is associated with clinically negligible concentrations of this bile acid in breast milk. Sci Rep 2022;12:19543. PubMed PMID: 36379995.
3. Ozdemir A, Kurtoglu S, Halis H, Bastug O. An evaluation of ursodeoxycholic acid treatment in prolonged unconjugated hyperbilirubinemia due to breast milk. Niger J Clin Pract 2023;26:1226-1233. PubMed PMID: 37794533.
4. Rudi J, Schonig T, Stremmel W. [Therapy with ursodeoxycholic acid in primary biliary cirrhosis in pregnancy]. Z Gastroenterol 1996;34:188-91. PubMed PMID: 8650973.
5. Brites D, Rodrigues CM. Elevated levels of bile acids in colostrum of patients with cholestasis of pregnancy are decreased following ursodeoxycholic acid therapy. J Hepatol 1998;29:743-51. PubMed PMID: 9833912.
6. Vítek L, Zelenkova M, Bruha R. Safe use of ursodeoxycholic acid in a breast-feeding patient with primary biliary cirrhosis. Dig Liver Dis 2010;42:911-2. PubMed PMID: 20619755.
7. Goh SK, Gull SE, Alexander GJ. Pregnancy in primary biliary cirrhosis complicated by portal hypertension: Report of a case and review of the literature. BJOG 2001;108:760-2. PubMed PMID: 11467706.
8. Efe C, Kahramanoglu-Aksoy E, Yilmaz B, et al. Pregnancy in women with primary biliary cirrhosis. Autoimmun Rev 2014;13:931-5. PubMed PMID: 24879082.
9. Erol-Coskun H, Karagur N, Akyol F, et al. Ursodiol use during breastfeeding: A case report. Reprod Toxicol 2018;80:59. Abstract.

Substance Identification

Substance Name

Ursodiol

CAS Registry Number

128-13-2

Drug Class

Breast Feeding

Lactation

Milk, Human

Bile Acids and Salts

Cholagogues and Choleretics

Cholic Acids

Gastrointestinal Agents