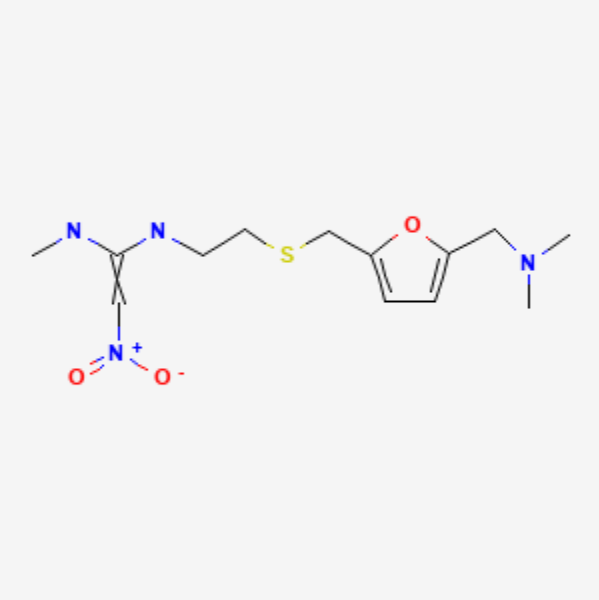
U.S. National Library of Medicine
National Center for Biotechnology Information

NLM Citation: Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Ranitidine. [Updated 2020 Sep 21].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Ranitidine

Revised: September 21, 2020.

CASRN: 66357-35-5



Drug Levels and Effects

Summary of Use during Lactation

Although interpatient variability exists, the dose of ranitidine in breastmilk is less than the dose used in newborn infants. However, the finding that ranitidine spontaneously breaks down to a cancer-causing chemical caused its removal from the market in the US and other countries. Other drugs are recommended.

Drug Levels

Maternal Levels. Six women with established lactation who were 6 to 10 days postpartum were given a single dose of 150 mg of ranitidine orally. Average milk levels were 1.28, 1.42 and 1.02 mg/L at 2, 4 and 8 hours,

respectively, after the dose; however, there was great interpatient variability in both peak levels and the time of the peak.[1]

After 5 oral doses of ranitidine 150 mg every 12 hours in a 54-day postpartum woman, the highest measured milk level occurred 5.5 hours after the 5th dose and was 2.6 mg/L. The estimated half-life in milk was 2.9 hours.[2]

Using the average peak milk level data from these 2 papers, an exclusively breastfed infant would receive an estimated maximum of 300 mcg/kg daily with a maternal dosage of 150 mg daily. This dosage is 20% of the dosage used intravenously in newborn infants for stress ulcer prophylaxis.

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

Effects in Breastfed Infants

One 54-day-old breastfed infant had no observable adverse effects after maternal ingestion of ranitidine 150 mg every 12 hours for 2 days.[2]

Effects on Lactation and Breastmilk

Histamine H2-receptor blockade is known to stimulate prolactin secretion.[3] Ranitidine in intravenous doses over 100 mg or during long-term oral use have increased serum prolactin in some studies, and rare cases of gynecomastia have been reported.[4-8] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Antacids, Cimetidine, Famotidine, Omeprazole, Pantoprazole, Sucralfate

References

1. Riley AJ, Crowley P, Harrison C. Transfer of ranitidine to biological fluids: Milk and semen. In: Misiewicz JJ, Wormsley KG, eds The clinical use of ranitidine Oxford: Medicine Publishing Foundation 1982:78-81.
2. Kearns GL, McConnell RF Jr, Trang JM, et al. Appearance of ranitidine in breast milk following multiple dosing. Clin Pharm. 1985;4:322–4. PubMed PMID: 4039999.
3. Knigge UP. Histaminergic regulation of prolactin secretion. Dan Med Bull. 1990;37:109–24. PubMed PMID: 2188799.
4. Perret G, Hugues JN, Louchahi M, et al. Effect of a short-term oral administration of cimetidine and ranitidine on the basal and thyrotropin-releasing hormone-stimulated serum concentrations of prolactin, thyrotropin and thyroid hormones in healthy volunteers. A double-blind cross-over study. Pharmacology. 1986;32:101–8. PubMed PMID: 3081918.
5. Delitala G, Devilla L, Pende A, et al. Effects of the H2 receptor antagonist ranitidine on anterior pituitary hormone secretion in man. Eur J Clin Pharmacol. 1982;22:207–11. PubMed PMID: 6125393.
6. Knigge U, Wollesen F, Dejgarrd A, et al. Comparison between dose-responses of prolactin, thyroid stimulating hormone and growth hormone to two different histamine H-2 receptor antagonists in normal men. Clin Endocrinol (Oxf). 1981;15:585–92. PubMed PMID: 6276054.
7. Tosi S, Cagnoli M. Painful gynecomastia with ranitidine. Lancet. 1982;2:160. PubMed PMID: 6123872.
8. Bera F, Jonville-Bera AP, Doustin P, et al. Therapie. 1994;49:361–2. [Impotence and gynecomastia secondary to hyperprolactinemia induced by ranitidine]. PubMed PMID: 7878608.

Substance Identification

Substance Name

Ranitidine

CAS Registry Number

66357-35-5

Drug Class

Breast Feeding

Lactation

Anti-Ulcer Agents

Histamine H2 Antagonists

Gastrointestinal Agents