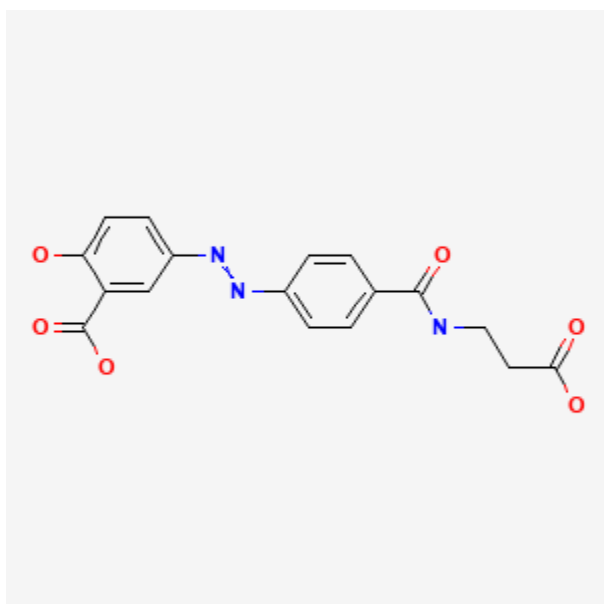




## Balsalazide

Revised: April 15, 2024.

CASRN: 80573-04-2



## Drug Levels and Effects

### Summary of Use during Lactation

Although no information exists on the excretion of balsalazide into breastmilk, it is metabolized to the active drug mesalamine. A few cases of diarrhea have been reported in infants exposed to mesalamine, although the rate is not high. Most experts and professional guidelines consider mesalamine derivatives to be acceptable during breastfeeding.[1-6] If balsalazide is required by the mother, it is not a reason to discontinue breastfeeding, but observe breastfed infants for diarrhea.

**Disclaimer:** Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

**Attribution Statement:** LactMed is a registered trademark of the U.S. Department of Health and Human Services.

## Drug Levels

Balsalazide is a prodrug that liberates the active drug, mesalamine (5-aminosalicylic acid; 5-ASA), in the gastrointestinal tract. Mesalamine is metabolized to N-acetyl-5-ASA, which is inactive in treating inflammatory bowel disease, but its possible effects on the breastfed infant are unknown.

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

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

## Effects in Breastfed Infants

The active metabolite of balsalazide, mesalamine, was probably responsible for diarrhea in a 6-week-old whose diarrhea recurred 4 times after rechallenging of the mother 4 times during breastfeeding.[7]

In a prospective telephone follow-up study, 8 nursing mothers reported taking mesalamine (dosage and route unspecified). One mother reported diarrhea in her infant. No other adverse reactions were reported in the infants by their mothers.[8]

A case-control study compared the infants of mothers taking mesalamine (n = 117; average dose, 2065 mg daily), olsalazine (n = 2) or sulfasalazine (n = 2) to infants of matched control mothers (n = 121) who were exposed to no treatment known to be harmful to a breastfed infant. Infants were exposed to mesalamine through milk for a mean of 5.3 months (range: 3 days-24 months). Infants were breastfed for an average of about 7.4 months and were followed up at an average age of about 22 months. No difference in the frequency or characteristics of maternally reported adverse events were found between exposed and control infants.[9,10]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

(Inflammatory Bowel Disease) [Adalimumab](#), [Azathioprine](#), [Budesonide](#), [Certolizumab Pegol](#), [Infliximab](#), [Mesalamine](#), [Prednisone](#), [Sulfasalazine](#)

## References

1. Nielsen OH, Maxwell C, Hendel J. IBD medications during pregnancy and lactation. *Nat Rev Gastroenterol Hepatol* 2014;11:116-27. PubMed PMID: 23897285.
2. Mahadevan U, Matro R. Care of the pregnant patient with inflammatory bowel disease. *Obstet Gynecol* 2015;126:401-12. PubMed PMID: 26241432.
3. Nguyen GC, Seow CH, Maxwell C, et al. The Toronto Consensus Statements for the Management of IBD in Pregnancy. *Gastroenterology* 2016;150:734-57.e1. PubMed PMID: 26688268.
4. van der Woude CJ, Ardizzone S, Bengtson MB, et al. The second European evidenced-based consensus on reproduction and pregnancy in inflammatory bowel disease. *J Crohns Colitis* 2015;9:107-24. PubMed PMID: 25602023.
5. Russell MD, Dey M, Flint J, et al. British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: Immunomodulatory anti-rheumatic drugs and corticosteroids. *Rheumatology (Oxford)* 2023;62:e48-e88. PubMed PMID: 36318966.
6. Torres J, Chaparro M, Julsgaard M, et al. European Crohn's and Colitis Guidelines on Sexuality, Fertility, Pregnancy, and Lactation. *J Crohns Colitis* 2023;17:1-27. PubMed PMID: 36005814.
7. Nelis GF. Diarrhoea due to 5-aminosalicylic acid in breast milk. *Lancet* 1989;333:383. Letter. PubMed PMID: 2563532.

8. Ito S, Blajchman A, Stephenson M, et al. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. *Am J Obstet Gynecol* 1993;168:1393-9. PubMed PMID: 8498418.
9. Moretti ME, Spiczynski Y, Hashemi G, et al. Prospective follow-up of infants exposed to 5-aminosalicylic acid containing drugs through maternal milk. *J Clin Pharmacol* 1998;38:867.  
doi:10.1177/009127009803800901
10. Moretti ME. Prospective follow-up of infants exposed to 5-aminosalicylic acid containing drugs through maternal milk. Theses Canada 1998. Available at: <https://library-archives.canada.ca/eng/services/services-libraries/theses/Pages/item.aspx?idNumber=51446896>

## Substance Identification

### Substance Name

Balsalazide

### CAS Registry Number

82101-18-6

### Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Inflammatory Agents, Non-Steroidal

Gastrointestinal Agents