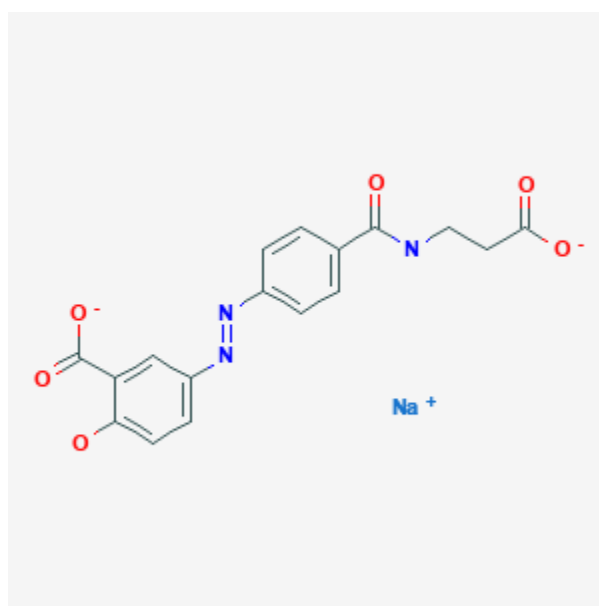




Balsalazide

Revised: October 31, 2018.

CASRN: 82101-18-6



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 consider mesalamine derivatives to be safe during breastfeeding.[1][2][3][4] If balsalazide is required by the mother, it is not a reason to discontinue breastfeeding, but observe breastfed infants for diarrhea.

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.

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 .

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 rechallenge of the mother 4 times during breastfeeding.[5]

Diarrhea has also been reported anecdotally by some nursing mothers taking mesalamine,[6] but a small controlled study reported only in abstract form found no higher rate of diarrhea in the breastfed infants of mothers taking mesalamine than in control infants.[7]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Mesalamine, 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. 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. Nelis GF. Diarrhoea due to 5-aminosalicylic acid in breast milk. *Lancet.* 1989;333:383. Letter. PubMed PMID: 2563532.
6. Ito S, Blajchman A, Stephenson M, Eliopoulos C, Koren G. 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.
7. 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. Abstract.

Substance Identification

Substance Name

Balsalazide

CAS Registry Number

82101-18-6

Drug Class

Breast Feeding

Lactation

Anti-Inflammatory Agents, Non-Steroidal

Gastrointestinal Agents