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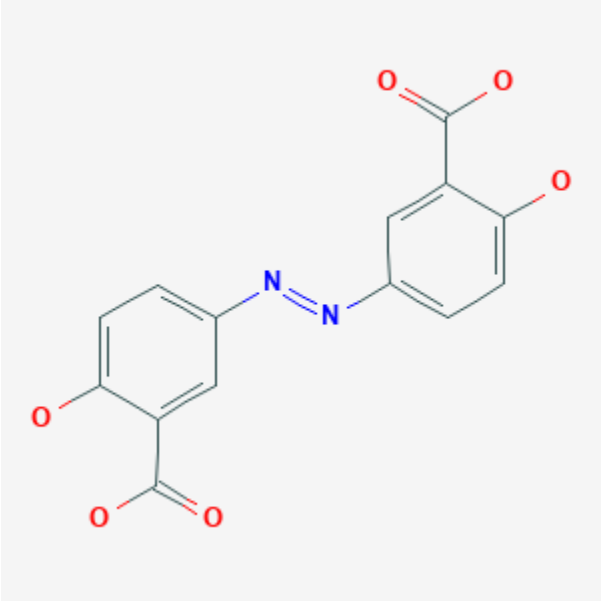
Olsalazine

Revised: October 31, 2018.

CASRN: 15722-48-2



Drug Levels and Effects

Summary of Use during Lactation

Limited data indicate that olsalazine is poorly excreted into breastmilk. However, olsalazine is a mesalamine prodrug. Rather high levels of the mesalamine metabolite N-acetyl-5-ASA appear in breastmilk and its effects on breastfed infants are unknown. 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 olsalazine is required by the mother, it is not a reason to discontinue breastfeeding, but carefully observe breastfed infants for diarrhea during maternal use of olsalazine.

Drug Levels

Olsalazine 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. A lactating woman with a long history of Crohn's disease and 2 bowel resections at her terminal ileum was given a single oral dose of olsalazine 500 mg at 4 months postpartum. She was also taking prednisone 17.5 mg daily at the time of the study. Milk samples were taken periodically from 30 minutes to 48 hours after the dose. Olsalazine and its metabolites, olsalazine sulfate and mesalamine were undetectable (<170 mcg/L) in milk at all times during the study. The inactive mesalamine metabolite, N-acetyl-5-ASA, was detectable only at 10, 14 and 24 hours after the dose in concentrations of 170, 183 and 264 mcg/L, respectively.[5]

A woman taking olsalazine capsules 750 mg twice daily collected 5 breastmilk samples during one day 2 to 4 weeks postpartum. Mesalamine was undetectable (<20 mcg/L) in milk. N-acetyl-5-ASA averaged 2.3 mg/L (range 1.2 to 3.8 mg/L) in the 5 samples. The highest milk level was in the 6 pm sample, but the times of the doses were not stated.[6]

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

Effects in Breastfed Infants

One infant was breastfed during maternal therapy with olsalazine for Crohn's disease. After 2 and 3 weeks of therapy, no rash, wheezing, vomiting or diarrhea were noted in the infant.[5]

The active metabolite of olsalazine, 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.[7]

Diarrhea has also been reported anecdotally by some nursing mothers,[8] 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.[9]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Mesalamine, Sulfasalazine

References

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Substance Identification

Substance Name

Olsalazine

CAS Registry Number

15722-48-2

Drug Class

Breast Feeding

Lactation

Gastrointestinal Agents

Anti-Inflammatory Agents, Non-Steroidal