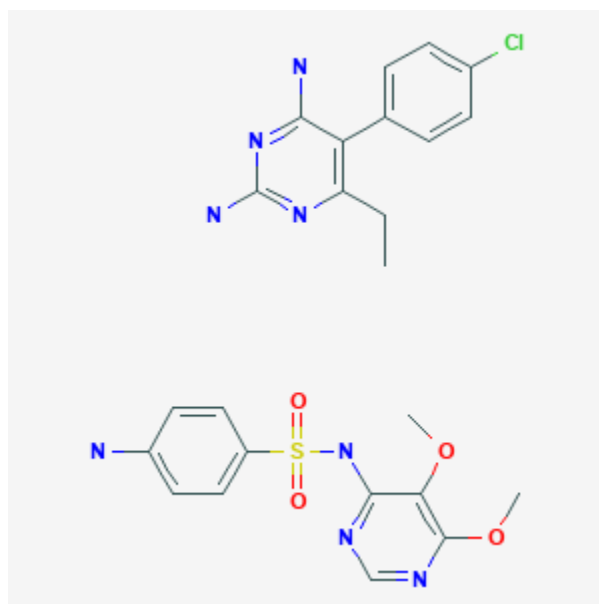




## Sulfadoxine and Pyrimethamine

Revised: December 3, 2018.

CASRN: 37338-39-9



## Drug Levels and Effects

### Summary of Use during Lactation

Because there is little published experience with sulfadoxine during breastfeeding, an alternate drug may be preferred, especially while nursing a newborn or preterm infant. The manufacturer states that the combination of sulfadoxine-pyrimethamine is contraindicated for prophylaxis during nursing and in children under 2 months of age. However, some authors have found no contraindication to the use of sulfadoxine-pyrimethamine during breastfeeding.[1][2] It has been suggested that maternal pyrimethamine clearance might be increased during lactation, but data are insufficient to make a definitive conclusion.[3][4]

Sulfadoxine-pyrimethamine prophylaxis of the mother should be discontinued at the first appearance in the infant of jaundice, skin rash, if a significant reduction in the count of any formed blood elements is noted, or upon the occurrence of active bacterial or fungal infections.

## Drug Levels

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

Pyrimethamine milk levels have been reported to range from 0.2 to 0.26 mcg/L 6 hours after a doses of 25, 50 or 75 mg in 6 women. Milk levels ranged from 0.125 to 0.155 mcg/L 24 hours after the dose and 0.095 to 0.0105 mcg/L at 48 hours.[5][6]

Three women were given a single dose of pyrimethamine 12.5 mg orally 2 to 5 days postpartum. Milk samples were obtained periodically for about 9 days after the dose. Assuming a daily intake of 1 L of milk, the infants would receive 0.14, 0.21 and 0.34 mg in milk over the study period. These values equate to an average of 46% of the maternal weight-adjusted dosage.[7]

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

## Effects in Breastfed Infants

Administration of pyrimethamine to mothers of 26 predominantly breastfed infants 2 to 6 months old who were infected with malaria was curative in the infants.[6] The regimen consisted of 75 mg followed by a subsequent dose of 50-75 mg 4 to 7 days later. The efficacy apparently is related to breastfeeding habits, because infants in another tribal group who breastfed their infants less extensively were not protected.[5] An additional case report indicates that a maternal dose of 75 mg orally followed by 25 mg weekly cured malaria in her infant and protected her breastfed infant against becoming infected with malaria for 6 months.[7] No adverse effects were reported in any of the infants.

A study of women with HIV infection being treated for presumptive malaria included 12 nursing mothers who were taking the sulfadoxine-pyrimethamine combination. The drug combination appeared to reduce breastmilk viral load less than chloroquine treatment. No mention was made of the effects in breastfed infants.[8]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

Chloroquine, Mefloquine

## References

1. Peters PJ, Thigpen MC, Parise ME, Newman RD. Safety and toxicity of sulfadoxine/pyrimethamine: implications for malaria prevention in pregnancy using intermittent preventive treatment. *Drug Saf.* 2007;30:481-501. PubMed PMID: 17536875.
2. Chattopadhyay R, Mahajan B, Kumar S. Assessment of safety of the major antimalarial drugs. *Expert Opin Drug Saf.* 2007;6:505-21. PubMed PMID: 17877439.
3. Salman S, Davis TME. Regarding "Lactation Status and Studies of Pyrimethamine Pharmacokinetics in Pregnancy". *CPT Pharmacometrics Syst Pharmacol.* 2017;6:730. PubMed PMID: 29064165.
4. de Kock M, Tarning J, Barnes KI, Denti P. Response to "Lactation Status and Studies of Pyrimethamine Pharmacokinetics in Pregnancy". *CPT Pharmacometrics Syst Pharmacol.* 2017;6:731. PubMed PMID: 29052341.
5. Clyde DF. An examination of factors involved in the transfer of pyrimethamine in human milk. *East Afr Med J.* 1957;34:81-5. PubMed PMID: 13437933.
6. Clyde DF, Press J, Shute GT. Transfer of pyrimethamine in human milk. *J Trop Med Hyg.* 1956;59:277-84. PubMed PMID: 13385913.

7. Clyde DF. Prolonged malaria prophylaxis through pyrimethamine in mothers' milk. *East Afr Med J.* 1960;37:659-60. PubMed PMID: 13694157.
8. Semrau K, Kuhn L, Kasonde P et al. Impact of chloroquine on viral load in breast milk. *Trop Med Int Health.* 2006;11:800-3. PubMed PMID: 16772000.

## Substance Identification

### Substance Name

Sulfadoxine and Pyrimethamine

### CAS Registry Number

37338-39-9

### Drug Class

Breast Feeding

Lactation

Anti-Infective Agents

Antiparasitic Agents

Antimalarials

Antiprotozoal Agents

Sulfonamides