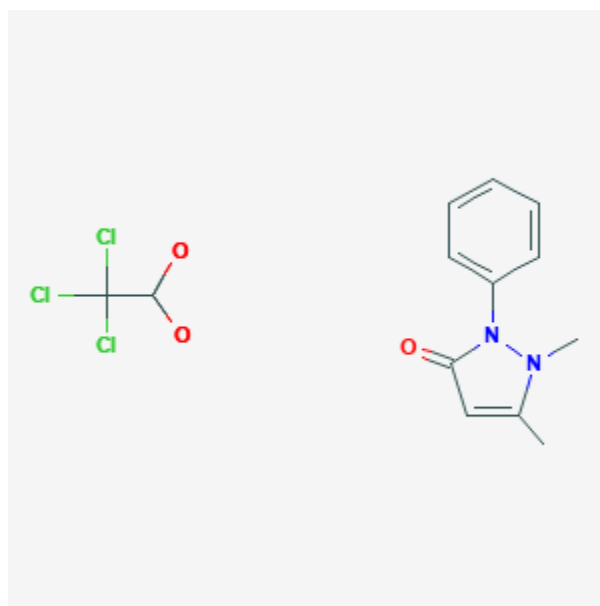




Dichloralphenazone

Revised: October 31, 2018.

CASRN: 480-30-8



Drug Levels and Effects

Summary of Use during Lactation

Short-term or occasional use of dichloralphenazone during breastfeeding is unlikely to adversely affect the breastfed infant, especially if the infant is older than 2 months. Because the active metabolite, trichloroethanol, has a long half-life, long-term use of repeated doses during breastfeeding could result in infant sedation, especially while nursing a neonate or preterm infant. The low doses of dichloralphenazone found in combination migraine products (e.g., Midrin) are less likely to cause drowsiness in the infant unless doses are repeated several times daily. The antipyrine component of dichloralphenazone is considered unlikely to harm the infant.[1][2] Monitor the infant for excessive drowsiness during use.

Drug Levels

Dichloralphenazone is a chemical combination of chloral hydrate (64%) and antipyrine (36%).

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. After 1.3 grams of dichloralphenazone (equivalent to about 830 mg of chloral hydrate) daily in a woman who was 5 month postpartum, milk trichloroethanol levels were found to range from 1.3 to 3.2 mg/L.[3]

Antipyrine was given to 7 lactating women were 2 to 19 months postpartum. Each woman drank a single oral dose of 18 mg/kg of antipyrine in solution. Peak milk levels usually occurred 10 minutes after ingestion and ranged from about 10 to 30 mg/L. The antipyrine half-life in milk averaged 11.6 hours (range 5.7 to 21.7 hours). The authors estimated that a fully breastfed infant would ingest 6.4 mg of antipyrine after this maternal dose or 0.59% of the maternal dose (not weight-adjusted). Two of the women who were studied before and after pregnancy indicated that antipyrine clearance might be increased by about two-fold during lactation.[1] The time course of antipyrine appearance in milk is probably slower than above from dichloralphenazone in a tablet formulation.

Infant Levels. After a 1.3 gram maternal dose of dichloralphenazone (equivalent to about 1 gram of chloral hydrate), trichloroethanol was detected in her 5-month-old breastfed infant's plasma 21 hours later.[3]

Effects in Breastfed Infants

Minimal morning sedation occurred in a 5-month-old breastfed infant whose mother was taking 1.3 grams of dichloralphenazone (equivalent to about 1 gram of chloral hydrate) every evening plus chlorpromazine 100 mg 3 times daily. The infant's overall development was said to be normal at 3 months of age.[3]

Effects on Lactation and Breastmilk

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

References

1. Berlin CM Jr, Vesell S. Antipyrine disposition in milk and saliva of lactating women. Clin Pharmacol Ther. 1982;31:38-44. PubMed PMID: 7053302.
2. Reed CB. A study of the conditions that require removal of the child from the breast. Surg Gynecol Obstet. 1908;6:514-27.
3. Lacey JH. Dichloralphenazone and breast milk. Br Med J. 1971;4:684. Letter. PubMed PMID: 5134581.

Substance Identification

Substance Name

Dichloralphenazone

CAS Registry Number

480-30-8

Drug Class

Breast Feeding

Lactation

Anti-Inflammatory Agents, Non-Steroidal

Hypnotics and Sedatives