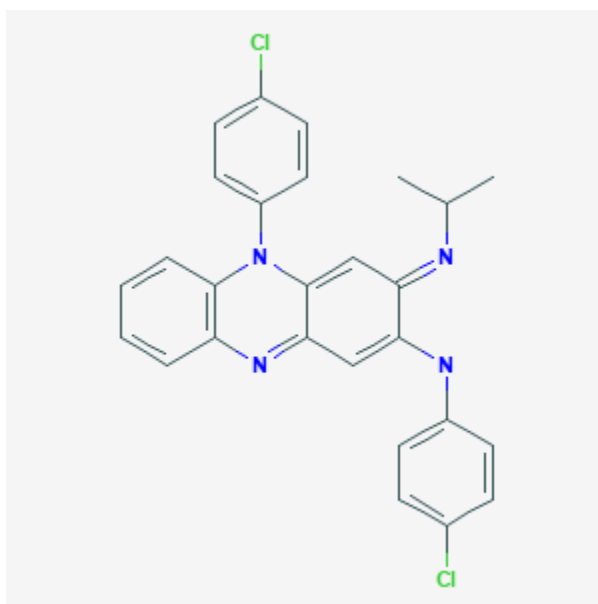




Clofazimine

Revised: October 31, 2018.

CASRN: 2030-63-9



Drug Levels and Effects

Summary of Use during Lactation

Limited information indicates that clofazimine appears in milk in relatively large amounts. Milk can be colored pink by the drug and breastfed infant's skin can be discolored the typical red color that is common in persons taking the drug. No serious or permanent toxicity has been reported in breastfed infants; however, an alternate drug might be considered.

Drug Levels

Clofazimine is excreted into milk, reportedly coloring it bright pink to red.[1][2]

Maternal Levels. Eight women with leprosy who had been breastfeeding for 4 months or less had been receiving clofazimine either 50 mg daily (n = 5), 100 mg every other day (n = 2) or 100 mg daily (n = 1) for an average of 5

months. Milk levels collected 4 to 6 hours after the dose averaged 1.33 mg/L (range 0.8 to 1.7 mg/L). Infants received an average of 0.199 mg/kg daily (range 0.17 to 0.26 mg/kg daily) which averaged 22.1% (range 13.5 to 30%) of the maternal weight-adjusted dosage.[3]

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

Effects in Breastfed Infants

Probable cases of skin discoloration in breastfed infants whose mothers were taking clofazimine have been reported. In one infant, red skin color was reported.[1] In another (exact maternal dosage not stated, but in the range of 100 to 300 mg daily), the infant's skin color was reported as ruddy and slightly hypermelanotic; this infant's skin color returned to normal 5 months after the end of maternal therapy.[4]

Clofazimine was used as part of a six-drug regimen to treat a pregnant woman with multidrug-resistant tuberculosis during the first trimester of pregnancy and postpartum. The infant was breastfed (extent and duration not stated). At age 1.8 years, the child had failure to thrive, possibly due to tuberculosis contracted after birth, but was otherwise developing normally. The child also had bronze coloration of the skin color which faded over time.[5]

A woman with leprosy took clofazimine, dapsone and rifampin during pregnancy and breastfeeding. Her infant developed skin discoloration attributed to clofazimine which reversed 3 months after cessation of breastfeeding.[6]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Dapsone

References

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4. Browne SG, Hogerzeil LM. "B 663" in the treatment of leprosy: preliminary report of a pilot trial. *Lepr Rev.* 1962;33:6-10. PubMed PMID: 13873759.
5. Drobac PC, del Castillo H, Sweetland A et al. Treatment of multidrug-resistant tuberculosis during pregnancy: long-term follow-up of 6 children with intrauterine exposure to second-line agents. *Clin Infect Dis.* 2005;40:1689-92. PubMed PMID: 15889370.
6. Ozturk Z, Tatliparmak A. Leprosy treatment during pregnancy and breastfeeding: A case report and brief review of literature. *Dermatol Ther.* 2017;30:e12414. PubMed PMID: 27549245.

Substance Identification

Substance Name

Clofazimine

CAS Registry Number

2030-63-9

Drug Class

Breast Feeding

Lactation

Leprostatic Agents