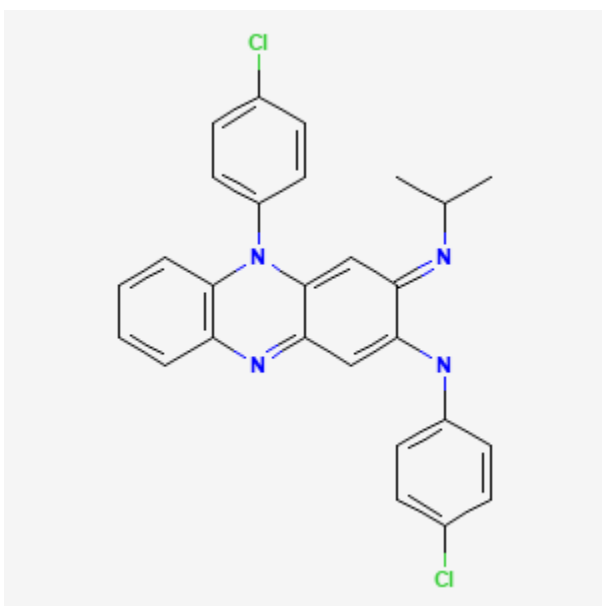




Clofazimine

Revised: September 15, 2023.

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. Human milk enhances the solubilization and possibly the absorption of clofazimine in infants.[1] Milk can be colored pink to red by the drug and breastfed infant's skin can be discolored the typical red color that is common in persons taking the drug.[2-4] No serious or permanent toxicity has been reported in breastfed infants; however, an alternate drug might be considered.

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Drug Levels

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.[5]

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.[6]

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. [7]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

(Leprosy) [Dapsone](#) (Cryptosporidiosis) [Nitazoxanide](#), [Paromomycin](#)

References

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Substance Identification

Substance Name

Clofazimine

CAS Registry Number

2030-63-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents

Leprostatic Agents