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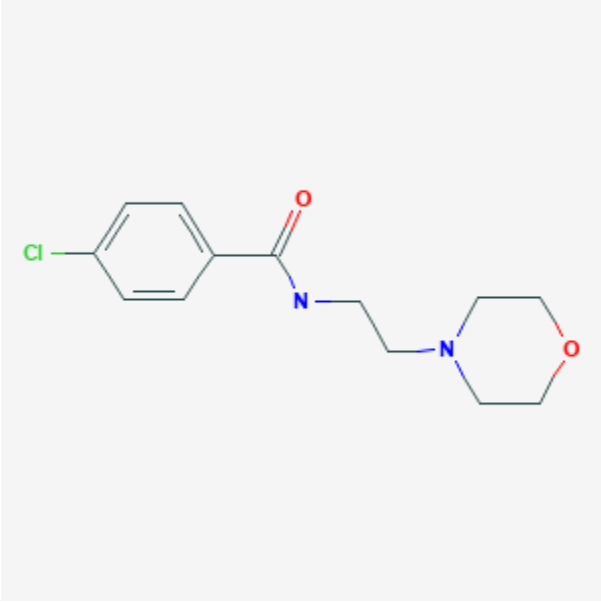
NLM Citation: Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. Moclobemide. [Updated 2018 Dec 3].
Bookshelf URL: https://www.ncbi.nlm.nih.gov/books/

Moclobemide

Revised: December 3, 2018.

CASRN: 71320-77-9



Drug Levels and Effects

Summary of Use during Lactation

Moclobemide is not approved for marketing in the United States by the U.S. Food and Drug Administration, but is available in other countries. Limited information indicates that maternal doses of moclobemide up to 900 mg daily produce low levels in milk. Although several breastfed infants apparently experienced no adverse effects during maternal use of moclobemide, no rigorous, long-term data are available. Until more data are available, moclobemide should only be used with careful monitoring during breastfeeding, especially while nursing a newborn or preterm infant.

Drug Levels

Maternal Levels. Six mothers who were 3 to 5 days postpartum were given a single dose of 300 mg of moclobemide by mouth. Milk samples were taken before the dose and 3, 6, 9, 12 and 24 hours after the dose.

Peak milk levels of moclobemide and its major inactive metabolite, Ro 12-8095, occurred 3 hours after the dose. The average 24-hour excretion of moclobemide in milk was 0.17 mg (range 0.11 to 0.28 mg) and of Ro 12-8095 was 0.1 mg (range 0.05 to 0.14 mg). The active metabolite, Ro 12-5637, was not detectable (assay limit not stated) in breastmilk. The authors estimated that this amount would be equal to approximately 1% of the weight-adjusted maternal dosage.[1]

Eight women were being treated for postpartum depression with moclobemide in daily dosages ranging from 300 mg to 900 mg. After at least 2 weeks of therapy, single blood and milk samples were collected from each patient within 4 hours after the dose. Average breastmilk levels were as follows: 300 mg daily (n = 2), 1.6 mg/L; 450 mg daily (n = 3), 1.24 mg/L; 600 mg daily (n = 2), 2 mg/L and 900 mg (n = 1) 5.3 mg/L. The Ro12-5637 metabolite was not detected and the Ro12-8095, was not quantified.[2] Using data in presented in the paper, the maximum amount of moclobemide that an infant would receive is estimated to be about 4% (range 2% to 6%) of the maternal weight-adjusted dosage. Average infant doses should be less than this.

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

Effects in Breastfed Infants

Nine women were being treated for postpartum depression with moclobemide in daily dosages ranging from 150 mg to 900 mg. All breastfed (extent not stated) their infants during therapy, but the duration of infant exposure to moclobemide in breastmilk was not stated. Maternal reports of infant weight gain, milestones and behavioral effects as well as clinical observation by the authors indicted no adverse effects in the breastfed infants.[2]

Four women who took moclobemide in dosages of 300 mg to 1200 mg daily during pregnancy were followed up in the neonatal period and at 1 year postpartum. All women breastfed (extent not stated) their infants. One woman ceased breastfeeding at 2 months postpartum because of severe gastroesophageal reflux in the infant; two other mothers breastfed beyond 12 months. The duration of breastfeeding in the fourth infant was not sated. All infants achieved developmental milestones.[3]

Effects on Lactation and Breastmilk

Moclobemide increases serum prolactin in males[4][5][6] and has caused galactorrhea in women.[7] The prolactin level in a mother with established lactation may not affect her ability to breastfeed.

References

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Substance Identification

Substance Name

Moclobemide

CAS Registry Number

71320-77-9

Drug Class

Breast Feeding

Lactation

Antidepressive Agents

Monoamine Oxidase Inhibitors