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Clozapine

Revised: October 31, 2018.

CASRN: 5786-21-0

Drug Levels and Effects

Summary of Use during Lactation

Because there is little published experience with clozapine during breastfeeding, and sedation and adverse hematologic effects have been reported in breastfed infants, other agents are preferred.[1] If breastfeeding is undertaken by a mother who is taking clozapine, close monitoring of the infant for excessive sedation and periodic monitoring of the infant's white blood cell count is advisable. Several authoritative sources recommend that women taking clozapine not breastfeed.[2][3][4]

Drug Levels

Maternal Levels. A woman taking oral clozapine 50 mg daily had a milk clozapine level of 63.5 mcg/L one day postpartum. At 3 days postpartum, her dose was increased to 100 mg/day and at 7 days postpartum, clozapine in

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milk was 115.6 mcg/L. Her infant was not breastfed and timing of the samples with respect to the doses was not stated.[5]

Infant Levels. One woman who took clozapine 100 mg daily in late pregnancy and postpartum partially breastfed her infant for 5 days. The umbilical cord blood clozapine concentration was 56% of the mother's plasma level at birth and infant's serum concentration was 6.5% of the mothers at 33 hours postpartum, implying no drug accumulation, but the timing of the sample with respect to the times of the dosage and nursing was not reported.

Effects in Breastfed Infants

Among 4 infants who were breastfed by mothers taking clozapine, 1 infant experienced drowsiness and 1 infant experienced agranulocytosis possibly caused by clozapine. Details of the cases are lacking.[7]

A healthy female infant was born to a mother who took clozapine 100 mg daily throughout pregnancy and lactation. She was breastfed (extent not stated) up to 1 year of age. The infant developed normally except for speech which was delayed considerably. She did not achieve normal, fluent speech until the age of 5 years. The delayed speech development was possibly related to clozapine in breastmilk, but it could have been the result of exposure to the drug during gestation or could have been unrelated to clozapine.[8]

One woman who took clozapine 100 mg daily in late pregnancy and postpartum partially breastfed her infant for 5 days. No neurodevelopmental disorders were detected in the infant after 32 months of follow-up.[6]

Effects on Lactation and Breastmilk

Unlike the phenothiazines, clozapine has a minimal effect on maternal serum prolactin levels.[9][10] However, a woman who had been taking clozapine plus high-dose haloperidol developed hyperprolactinemia and severe galactorrhea 2 weeks after stopping haloperidol and 4 days after starting valproic acid. A dose of cabergoline normalized her serum prolactin and galactorrhea ceased for the following 2 months of observation.[11]

The maternal prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Alternate Drugs to Consider

Haloperidol, Olanzapine, Quetiapine, Risperidone

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Substance Identification

Substance Name

Clozapine

CAS Registry Number

5786-21-0

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents