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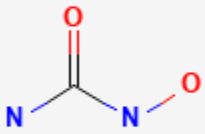
Hydroxyurea

Revised: January 15, 2024.

CASRN: 127-07-1



Drug Levels and Effects

Summary of Use during Lactation

Most sources consider breastfeeding to be contraindicated during maternal antineoplastic drug therapy, although the evidence for this recommendation for hydroxyurea is very weak.[1,2] Chemotherapy may adversely affect the normal microbiome and chemical makeup of breastmilk.[3]

Drug Levels

Maternal Levels. A mother was taking 500 mg of hydroxyurea orally three times a day. Milk samples taken 2 hours after the last dose of each day on 3 days averaged 6.1 mg/L (range 3.8 to 8.4 mg/L). Using these data, the infant in this case would have received less than 4% of maternal weight-adjusted dosage.[4]

Using a more modern assay, investigators measured hydroxyurea in a mother who was taking an oral dose of 1 gram once daily. Nine milk samples were taken over a 3-day period. Trough milk levels ranged from 0.51 to 1.23 mg/L and the highest level was 19.24 mg/L at 3 hours after the dose on one day. All other measurements fell between these values.[5]

Sixteen lactating mothers, 2 with sickle cell disease, were given 1 gram of hydroxyurea orally. Mothers were a median of 8.6 months (range 2.5 to 22.1 months) postpartum. Milk samples were collected before the dose and at 10 time points over the next 12 hours. A further milk sample obtained at 24 hours after the dose contained no detectable drug (<5 mg/L). Peak plasma levels averaging 12.9 mg/L (range 6.2 to 23 mg/L) occurred at a mean of 2.2 hours (range 0.9 to 3.6 hours) after the dose. Milk levels averaged about 84% of plasma levels and closely paralleled plasma levels. There was no difference between the patients and normal volunteers. The authors calculated that an average of 2.2 mg (0.41 mg/kg) was excreted into breastmilk over 24 hours, but 1.2 mg of this was in the first 3 hours. A pharmacokinetic model created using these data predicted that the daily dosage that an infant would receive would be 0.46 mg/kg daily or 3.4% of the maternal weight-adjusted dosage. By avoiding breastfeeding for 3 hours after the dose, the amount of drug transferred to the infant would be cut in half.[6]

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

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

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

References

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Substance Identification

Substance Name

Hydroxyurea

CAS Registry Number

127-07-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Antineoplastic Agents

Antisickling Agents

Enzyme Inhibitors

Nucleic Acid Synthesis Inhibitors