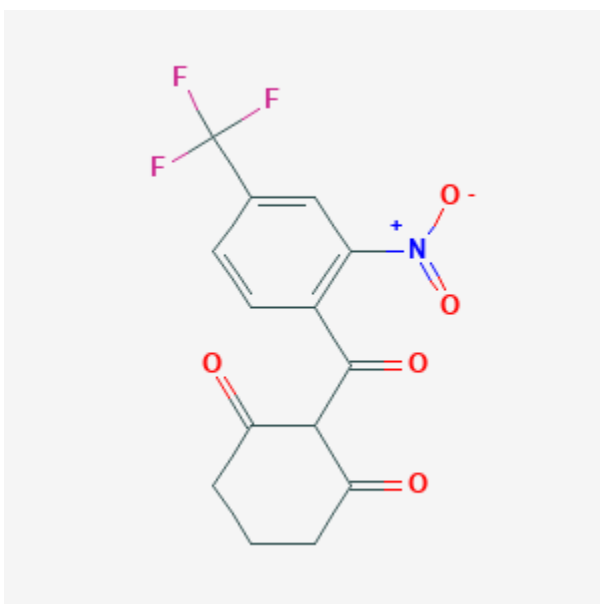




Nitisinone

Revised: March 21, 2022.

CASRN: 104206-65-7



Drug Levels and Effects

Summary of Use during Lactation

Blood levels in two exclusively breastfed infants of one mother were far below the therapeutic range and dropped from the initial postpartum measurement to levels taken during the second week of breastfeeding. The infants had no adverse reactions and grew normally. If nitisinone is required by the mother, it is not a reason to discontinue breastfeeding. Until more data are available, monitoring the breastfed infant's blood nitisinone, tyrosine and succinylacetone concentrations might be advisable.[1]

Drug Levels

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

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Infant Levels. A mother was taking nitisinone 40 mg daily for type-1 tyrosinemia during pregnancy and breastfeeding. The infant's mother breastfed exclusively for 2 weeks. Two days postpartum, the infant's blood nitisinone concentration was 10.9 micromoles/L. Because of the drug's long half-life of 54 hours, this concentration was probably from transplacental passage. The blood level dropped to 1.7 micromoles/L at about 10 days postpartum and at 6 weeks, nitisinone was undetectable (<0.1 micromoles/L) in the infant's blood. A second infant of the same mother was born when the mother was taking nitisinone 80 mg daily. The infant was exclusively breastfed exclusively for 2 weeks. The infant's blood nitisinone concentration was 5 micromoles/L on day 5 of life, 1.7 micromoles/L at about day 12 of life and undetectable on day 24 of life. All of the measured infant blood levels were far below the therapeutic reference range for infants of 30 to 60 micromoles/L.[1]

Effects in Breastfed Infants

A patient with type-1 tyrosinemia was taking nitisinone 40 mg daily or 0.44 mg/kg daily in addition to a low tyrosine and phenylalanine diet. She continued on this regimen during her first pregnancy and postpartum. In her second pregnancy, the nitisinone dosage was increased to 60 mg daily in the week 11 of pregnancy, to 80 mg daily in the week 28 and continued at that dosage postpartum. Both infants were exclusively breastfed for 2 weeks postpartum. They showed no adverse reactions and grew normally.[1]

Effects on Lactation and Breastmilk

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

References

1. Zöggeler T, Ramoser G, Höller A, et al. Nitisinone treatment during two pregnancies and breastfeeding in a woman with tyrosinemia type 1 - a case report. *J Pediatr Endocrinol Metab.* 2022;35:259–65. PubMed PMID: 34506697.

Substance Identification

Substance Name

Nitisinone

CAS Registry Number

104206-65-7

Drug Class

Breast Feeding

Lactation

Enzyme Inhibitors