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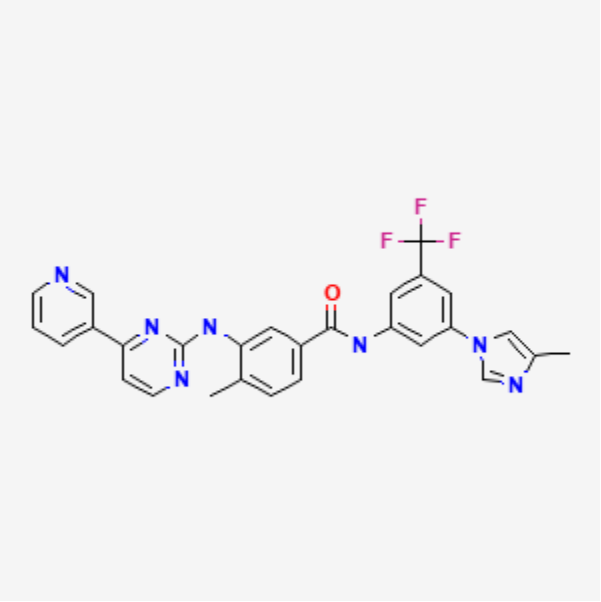
Nilotinib

Revised: April 15, 2024.

CASRN: 641571-10-0



Drug Levels and Effects

Summary of Use during Lactation

Although the amount of nilotinib in milk appears to be small and one breastfed infant apparently experienced no adverse effects during maternal use of nilotinib, no long-term data are available. Because nilotinib is 98% bound to plasma proteins, the amounts in milk are likely to be low. However, there is little published experience with nilotinib during breastfeeding, and an alternate drug may be preferred, especially while nursing a newborn or preterm infant. National Comprehensive Cancer Network guidelines recommend avoiding breastfeeding during nilotinib therapy and the manufacturer recommends withholding breastfeeding until 2 weeks following the last dose.[1]

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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Drug Levels

Maternal Levels. One woman with Ph+ chronic myelocytic leukemia was taking nilotinib before pregnancy, but stopped until breastfeeding ceased. She received one dose of nilotinib 400 mg orally and took milk samples at 1, 2, 4, 6, 8, 12 and 24 hours after the dose. She had a peak milk concentration of 129 mcg/L at 4 hours after the dose.[2] These data were incorporated into a physiologically based pharmacokinetic model that predicted the pharmacokinetic profile relatively well. However, more data are needed to validate the model.[3]

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

Effects in Breastfed Infants

A woman with chronic myeloid leukemia received nilotinib (dosage not stated) for 20 months before pregnancy, throughout pregnancy and continuing during 9 months of breastfeeding (extent not stated). No adverse reactions were reported in her breastfed infant.[4]

Effects on Lactation and Breastmilk

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

Alternate Drugs to Consider

Imatinib

References

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2. Chelysheva E, Aleshin S, Polushkina E, et al. Breastfeeding in patients with chronic myeloid leukaemia: Case series with measurements of drug concentrations in maternal milk and literature review. Mediterr J Hematol Infect Dis 2018;10:e2018027. PubMed PMID: 29755704.
3. Liu XI, Leong R, Burckart GJ, Dallmann A. Physiologically-based pharmacokinetic modeling of nilotinib for drug-drug interactions, pediatric patients, and pregnancy and lactation. J Clin Pharmacol 2024;64:323-33. PubMed PMID: 37909674.
4. Alizadeh H, Jaafar H, Kajtar B. Outcome of 3 pregnancies in a patient with chronic myeloid leukemia who received 3 types of tyrosine kinase inhibitors each in different pregnancy: Follow-up of the case with a review of published reports. Ann Saudi Med 2015;35:468-71. PubMed PMID: 26657232.

Substance Identification

Substance Name

Nilotinib

CAS Registry Number

641571-10-0

Drug Class

Breast Feeding

Lactation

Milk, Human

Antineoplastic Agents

Enzyme Inhibitors

Protein Kinase Inhibitors

Signal Transduction Inhibitors

Tyrosine Kinase Inhibitors