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Filgrastim

Revised: June 3, 2019.

CASRN: 121181-53-1

Drug Levels and Effects

Summary of Use during Lactation

Filgrastim in the pharmaceutical name for granulocyte colony-stimulating factor (G-CSF). Pegfilgrastim is the long-acting form of filgrastim. The excretion of exogenous G-CSF into breastmilk or its effects on breastfed infants have not been well studied. Limited data indicate that filgrastim and a similar G-CSF product, lenograstim, are poorly excreted into breastmilk and are undetectable by 3 days after an injection. Some authors recommend withholding breastfeeding for this period of time.[1] However, filgrastim has been safely given orally to neonates and is not orally absorbed by neonates, so any filgrastim that is excreted into milk is unlikely to adversely affect the breastfed infant.

Drug Levels

Granulocyte colony-stimulating factor (G-CSF) is a normal component of breastmilk. In the United States, the biosynthetic forms that are available for exogenous administration are filgrastim and pegfilgrastim. Other biosynthetic forms of G-CSF are available in other countries. Lenograstim is a glycosylated recombinant G-CSF whereas filgrastim is not glycosylated.

Maternal Levels. A nursing mother who was 4 months postpartum was given the recombinant G-CSF product lenograstim in order to donate peripheral blood stem cells. She was given lenograstim subcutaneously in doses of 300 mcg on day 1,600 mcg daily on days 2 to 4 and 300 mcg daily on days 5 and 6 of therapy. G-CSF concentration in milk was less than 5 ng/L before therapy. G-CSF milk levels increased during therapy with levels of about 58 ng/L on day 4, 78 ng/L on day 5, and 85.7 ng/L on day 6. Sampling times were not stated.[2] The maximum amount in milk represents an infant dosage of about 0.013 mcg/kg which is 13% of an infant subcutaneous dose of exogenous G-CSF and 0.13% of the maternal weight-adjusted dosage.

A woman received subcutaneous injections of filgrastim in the following doses: 600 mcg on day 1,300 mcg twice daily on days 2 to 5, and 300 mcg once on day 6 prior to harvesting white cells for donation. She was nursing her 25-day-old infant and milk G-CSF levels were measured once daily just before the first dose of the day. G-CSF was first detectable (>10 ng/L) in whole milk 12 hours after the start of the regimen, had a peak milk

concentration of 188 ng/L at 22 hours after the start of the regimen, and then after 43 hours, slowly declined until G-CSF was undetectable (<10 ng/L) in breastmilk 70 hours after the last dose.[3]

A patient received granulocyte colony stimulating factor (presumably filgrastim) for hematopoietic progenitor cell mobilization prior to transplantation. The exact dosage and regimen were not stated in the published abstract. The peak concentration of G-CSF in donor milk was at 592 ng/L 48 hours after the first dose. G-CSF remained detectable in donor milk for 48 hours after the final dose.[4]

Infant Levels. Published information on absorption of filgrastim from breastmilk was not found as of the revision date. However, a study in which an oral dose of 100 mcg/kg of filgrastim (10 times the subcutaneous dose) was given to preterm infants found that filgrastim was not absorbed.[5]

Effects in Breastfed Infants

Published information on the effects of filgrastim in breastmilk was not found as of the revision date. However, oral filgrastim 20 mcg daily for 5 days has been given to preterm infants with stage I necrotizing enterocolitis (NEC). Filgrastim appeared to halt progression to more severe stages of NEC in this small study.[6]

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

Filgrastim

CAS Registry Number

121181-53-1

Drug Class

Breast Feeding

Lactation

Colony-Stimulating Factors

Hematopoietic Cell Growth Factors

Pegfilgrastim-cbqv