



Sargramostim

Revised: October 15, 2023.

CASRN: 123774-72-1

Drug Levels and Effects

Summary of Use during Lactation

Sargramostim is a slightly modified, glycosylated form of granulocyte-macrophage colony-stimulating factor (GM-CSF). GM-CSF is a normal component of breastmilk, probably generated in milk by breastmilk macrophages.[1,2] However, breastfed infants do not have greater serum GM-CSF serum levels than formula-fed infants and neutrophil activation resulting from GM-CSF is no different between breastfed and formula-fed infants. These lacks of differences are probably because GM-CSF is a large molecule with a molecular weight of 23,000 Da and is probably partly digested in the infant's gastrointestinal tract and poorly absorbed by the infant. No information is available on the use of intravenous sargramostim in nursing mothers, but breastmilk levels of GM-CSF were not increased in one nursing mother after receiving inhaled sargramostim. Maternal sargramostim is unlikely to adversely affect her breastfed infant.

Drug Levels

Maternal Levels. Twenty nursing mothers of full-term infants provided milk samples at 5 days postpartum. The average concentration of GM-CSF in their milk was 100 ng/L.[3]

A woman with autoimmune pulmonary alveolar proteinosis caused by GM-CSF autoantibodies was treated with inhaled sargramostim 250 mcg daily. GM-CSF was undetectable in milk both before and 8 hours after receiving inhaled sargramostim.[4]

Infant Levels. Twenty breastfed and 13 formula-fed full-term infants had serum concentration of GM-CSF measured at 5 days of age. Breastfed infants had an average GM-CSF concentration of 33.5 ng/L and formula-fed infants had an average GM-CSF serum concentration of 18.9 ng/L, but this difference was not statistically significant. In addition, no difference was found in neutrophil chemotaxis between the two groups and no correlations were found between GM-CSF concentrations in milk or infants' sera and neutrophil chemotaxis.[3]

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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

1. Garofalo R. Cytokines in human milk. *J Pediatr* 2010;156 (2 Suppl):S36-S40. PubMed PMID: 20105664.
2. Ichikawa M., Sugita M., Takahashi M., et al. Breast milk macrophages spontaneously produce granulocyte-macrophage colony-stimulating factor and differentiate into dendritic cells in the presence of exogenous interleukin-4 alone. *Immunology* 2003;108:189-95. PubMed PMID: 12562327.
3. Gasparoni A., Chirico G., De Amici M., et al. Granulocyte-macrophage colony-stimulating factor in human milk. *Eur J Pediatr* 1996;155:69. PubMed PMID: 8750819.
4. Roach M, Chalk C, Stock J, et al. Risk of autoimmune PAP caused by passive transfer of GM-CSF autoantibodies during breast feeding: A case report. *Am J Respir Crit Care Med* 2023;207 (Suppl S):A4940. doi:10.1164/ajrccm-conference.2023.207.1_MeetingAbstracts.A4940

Substance Identification

Substance Name

Sargramostim

CAS Registry Number

123774-72-1

Drug Class

Breast Feeding

Lactation

Milk, Human

Hematopoietic Cell Growth Factors

Colony-Stimulating Factors

Immunologic Factors