

FILLIF-PEG

For the use of Oncologist or a Hospital or a Laboratory only

Abbreviated Prescribing information for Fillif-PEG Pegfilgrastim Injection PFS 6 mg) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: It is a Pegylated Recombinant Granulocyte Colony Stimulating Factor that acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

INDICATIONS: To decrease the incidence of infection, as manifested by febrile neutropenia.

DOSAGE AND ADMINISTRATION: It is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle generally between 24-36 hours after the last dose of the chemotherapy cycle. (Pegfilgrastim) should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

CONTRAINDICATIONS: Hypersensitivity to E coli - derived proteins, Pegfilgrastim, filgrastim, or any other component of the product.

WARNINGS AND PRECAUTIONS: Splenic Rupture, Adult Respiratory Distress Syndrome (ARDS), Allergic Reactions, Sickle Cell Disease Precautions: Use with chemotherapy and / or Radiation therapy, Filgrastim can act as a growth factor for any tumor type. In order to avoid the potential complications of excessive leukocytosis, a CBC is recommended twice per week during therapy.

DRUG INTERACTIONS: Lithium potentiates the effect of drug, regular monitoring of CBC is required.

ADVERSE REACTIONS: Medullary bone pain, Reversible increase in LDH, alkaline phosphatase, and uric acid, nausea, vomiting, fatigue, alopecia, Diarrhea, constipation, fever, anorexia, skeletal pain, headache, taste perversion, dyspepsia, myalgia, insomnia, abdominal pain, arthralgia, generalized weakness, peripheral edema, dizziness, granulocytopenia, stomatitis, mucositis, and neutropenic fever