

FILLIF-PEG®

For the use of oncologists, hematologists or physicians and pediatricians experienced in treatment of cancer only

Abbreviated Prescribing information for FILLIF-PEG® [Pegfilgrastim Injection I.P. (6 mg/0.6 ml Prefilled Syringe)]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Pegfilgrastim is a colony-stimulating factor which increases the proliferation and differentiation of neutrophils from committed progenitor cells, induces maturation, and enhances the survival and function of mature neutrophils, resulting in dose-dependent increases in neutrophils.

INDICATIONS: *Patients with Cancer Receiving Myelosuppressive Chemotherapy* - FILLIF-PEG® is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. FILLIF-PEG® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. *Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome* - FILLIF-PEG® is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

DOSAGE AND ADMINISTRATION: *Patients with Cancer Receiving Myelosuppressive Chemotherapy* -. The recommended dosage of FILLIF-PEG® is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. *Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome* - The recommended dose of FILLIF-PEG® is two doses, 6 mg each, administered subcutaneously one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose. For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg), for 10 -20 kg, administer 0.15 mL/kg, for 21 -30 kg, administer 0.25 mL/kg, for 31 -44 kg administer 0.40 mL/kg. FILLIF-PEG® is administered subcutaneously via a single prefilled syringe. The direct administration to patients requiring dosing of less than 0.6 mL (6 mg) is not recommended due to the potential for dosing errors.

CONTRAINDICATION: Known hypersensitivity to pegfilgrastim, filgrastim, any ingredient in the formulation or proteins derived from Escherichia coli.

WARNINGS & PRECAUTIONS: Splenic rupture, including fatal cases, can occur following the administration of FILLIF-PEG®. Acute respiratory distress syndrome (ARDS) can occur in patients receiving FILLIF-PEG®. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue FILLIF-PEG® (Pegfilgrastim Injection) in patients with serious allergic reactions. Do not administer FILLIF-PEG® (Pegfilgrastim Injection) to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. Severe sickle cell crises can occur in patients with sickle cell disorders. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption. Monitoring of complete blood count (CBC) during pegfilgrastim therapy is recommended. Capillary leak syndrome has been reported after G-CSF administration and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment. Aortitis has been reported in patients receiving pegfilgrastim. Discontinue pegfilgrastim if aortitis is suspected.

DRUG INTERACTIONS: Possible potentiation of neutrophil release with lithium. Sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy may be increased.

ADVERSE REACTIONS: Anaemia, febrile neutropenia, leukopenia, neutropenia, pancytopenia, vertigo, abdominal pain, ascites, constipation, diarrhoea, enteritis, hyperchlorhydria, nausea, painful defaecation, salivary hypersecretion, stomatitis, vomiting, asthenia, disease progression, injection site pain, mucosal inflammation, pain, pyrexia, cellulitis, herpes zoster, red blood cells urine positive, urinary sediment abnormal, weight decreased, white blood cell count increased, white blood cells urine positive, decreased appetite, back pain, bone pain, joint range of motion decreased, musculoskeletal pain, headache, neuropathy peripheral, peripheral sensory neuropathy, pyuria, cough, pleural effusion, alopecia, alopecia totalis, skin discolouration, skin hyperpigmentation, haemorrhage, fatigue, fever, anorexia, taste perversion, dyspepsia, insomnia, arthralgia, generalized weakness, peripheral edema, dizziness, granulocytopenia, and mucositis.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/FILLIF-PEG® 6 mg/0.6 ml /MAR 2026/02/ABPI

(Additional information is available on request)