# FILLIF

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

Abbreviated Prescribing information for FILLIF (Filgrastim Injection PFS 300 mcg (Recombinant Human Granulocyte Colony Stimulating Factor Injection (G-CSF)) [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: Recombinant G-CSF (Filgrastim), the active ingredient of FILLIF, is a protein having the structure of the granulocyte colony-stimulating factor (G-CSF) produced and secreted by various human blood cell types.

**INDICATIONS:** Cancer patients receiving myelosuppressive chemotherapy: Recombinant G-CSF 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 significant incidence of severe neutropenia with fever. In patients with acute myeloid leukemia receiving induction or consolidation chemotherapy recombinant G-CSF is indicated for reducing the time to neutrophil recovery and the duration of fever. Cancer patients receiving bone marrow transplant indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg. febrile neutropenia, in-patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation. Patients undergoing peripheral blood progenitor cell collection and therapy-for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

**DOSAGE AND ADMINISTRATION:** Cancer patients receiving myelosuppressive chemotherapy: The recommended starting dose is 5 mcg/kg/day, administered as a single daily injection by SC bolus injection, by short IV infusion (15 to 30 minutes) , or by continuous SC or continuous IV infusion. Cancer patients receiving bone marrow transplant**:** The recommended dose is 10 mcg/kg/day given as an IV infusion of 4 or 24 hours, or as a continuous 24-hour SC infusion. Peripheral blood progenitor cell collection and therapy in cancer patients**:** The recommended dose is 10 mcg/kg/day SC, either as a bolus or a continuous infusion.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients. FILLIF should not be administered to patients with severe congenital neutropenia (Kostman's syndrome) with abnormal cytogenetics.

**WARNINGS & PRECAUTIONS:** Allergic reactions, enlarged spleen or splenic rupture, cutaneous vasculitis , acute respiratory distress syndrome, alveolar hemorrhage and hemoptysis and sickle cell disorders. Do not use filgrastim in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy. Special caution should be used when treating patients with high dose chemotherapy, because improved tumour outcome has not been demonstrated and intensified doses of chemotherapeutic agents may lead to increased toxicities including cardiac, pulmonary, neurologic, and dermatologic effects, premature discontinuation of Recombinant G-CSF (Filgrastim) therapy, prior to the time of recovery from the expected neutrophil nadir, is generally not recommended.

**DRUG INTERACTIONS:** Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. Preliminary evidence from a small number of patients treated concomitantly with Recombinant G-CSF (Filgrastim) and 5-Fluorouracil indicates that the severity of neutropenia may be exacerbated. Lithium is likely to potentiate the effect of Recombinant G-CSF (Filgrastim).

**ADVERSE REACTIONS**: Sweet's syndrome (acute febrile neutrophilic dermatosis), ,musculoskeletal pain, anaemia, fatigue, asthenia, administration site mucosal inflammation, chest pain, conditions injection site pain, increased blood alkaline phosphatase, gamma-glutamyl transferase, blood lactate dehydrogenase, aspartate aminotransferase and blood uric acid, blood glucose decreased, hyperuricemia, epistaxis, nausea and vomiting.

**MARKETED BY:**

torrent PHARMA

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**IN/ FILLIF 300 mcg/Jun-15/01/AbPI**
(Additional information is available on request)