



For the use of a Registered Medical Practitioner, Hospital or a Laboratory

GRAFEEL™
Filgrastim Injection
(Human Recombinant Granulocyte
Colony Stimulating Factor)

COMPOSITION

Grafeel

Each 1 ml vial contains:
Filgrastim (rhG-CSF) 300 mcg or 30 MU as active ingredient.

Filgrastim is a highly purified non-glycosylated protein comprising of 175 amino acids. Filgrastim is produced in laboratory by strains of Escherichia coli, genetically altered by the addition of a gene for the human granulocyte colony-stimulating factor (rhG-CSF).

Excipients: sodium acetate buffer (pH 4.0), sorbitol, polysorbate 80, water for injection.

Indications:

- ❖ Decreasing the severity of cytotoxic chemotherapy induced neutropenia.
- ❖ The acceleration of myeloid recovery in patients following autologous or syngeneic bone marrow transplantation.
- ❖ In treatment or prophylaxis of leukopenia associated with myelosuppressive therapies. In patients associated with bone marrow failure states. It is also indicated for the treatment of associated leukopenia.

Dosage:

- ❖ Prophylaxis of chemotherapy-induced neutropenia in patients receiving myelosuppressive chemotherapy and to decrease the incidence of febrile neutropenia:
 - Patients with a previous episode of febrile neutropenia (secondary prophylaxis) or as primary prophylaxis in patients receiving chemotherapy regimens with an expected incidence of febrile neutropenia above 40% or in the presence of co-morbid factors:

Adults: 5 mcg/kg/day IV/SC or by continuous SC or IV infusion. Dosage may be rounded to the nearest vial size. Starting Filgrastim therapy within 24-72 hours following chemotherapy provides optimal neutrophil recovery. Therapy should be continued for 7-14 days, until the absolute neutrophil count (ANC) reaches 10,000/mm³ following the expected chemotherapy-induced nadir. However, a shorter duration of administration that is sufficient to achieve clinically adequate neutrophil count is a reasonable alternative. Some clinicians monitor the total WBC (as opposed to the ANC) and discontinue Filgrastim when the total WBC is > 10,000 cells/mm³. Other clinicians stop Filgrastim when the ANC is > 1500/mm³ for 3 consecutive days.

- ❖ For patients with nonmyeloid malignancies, following autologous bone marrow transplantation (BMT), to reduce the duration of neutropenia and febrile neutropenia:

- Adults: 10 mcg/kg/day IV/SC or by continuous SC or IV infusion. The first dose should be administered at least 24 hours after the last dosage of cytotoxic chemotherapy, and at least within 24 hours of bone marrow infusion. The following dosage titration is recommended during the neutrophil recovery period:
- If the ANC > 1000/mm³ for 3 consecutive days, reduce dose to 5 mcg/kg/day;
- If the ANC remains > 1000/mm³ for 3 consecutive days following dosage reduction, discontinue drug. If the ANC decreases to < 1000/mm³ following dose reduction or discontinuation, increase dose to 10 mcg/kg/day or resume Filgrastim at 5 mcg/kg/day, respectively, and follow previous steps.

Patients with hepatic or renal impairment:

There is insufficient information on the use of Filgrastim in patients with impaired renal or hepatic function. Therefore, its use in such patients is not recommended.

Administration Guidelines:

Filgrastim is administered as a subcutaneous injection or as a subcutaneous/intravenous infusion. For infusion, it should be diluted with up to 20 mL of 5% dextrose to achieve a concentration of 5-15 mg/mL. Addition of human albumin to the solution to a concentration of 2 mg/mL helps prevent adsorption of Filgrastim on plastic tubing or glass bottles used in the infusion.

Filgrastim should not be diluted with 0.9% sodium chloride solution.

Intravenous infusion may be administered either over 30 minutes or over 24 hours. Subcutaneous infusion should be administered over 24 hours.

Storage:

Store between 2-8°C. Do not freeze.

Presentation:

Filgrastim is available as 1mL vial containing 300 mg (30 MU) of Filgrastim.

Full Prescribing Information is available to the medical profession on request.