



Filgrastim 300 mcg (30 MU)

COMPOSITION

Each pre-filled syringe contains 0.5 ml solution containing Filgrastim INN 300 mcg (30 MU).

PHARMACOLOGICAL INFORMATION

Filgrast (Filgrastim) is a granulocyte colony-stimulating factor (G-CSF) analog used to stimulate the proliferation and differentiation of granulocytes. It is produced by recombinant DNA technology. The gene for human granulocyte colony-stimulating factor is inserted into the genetic material of *Escherichia coli*. The G-CSF then produced by *E. coli* is only slightly different from G-CSF naturally made in humans.

Clinical Pharmacology

Colony-stimulating factors are glycoproteins which act on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment and some end-cell functional activation. Endogenous G-CSF is a lineage specific colony-stimulating factor which is produced by monocytes, fibroblasts, and endothelial cells. G-CSF regulates the production of neutrophils within the bone marrow and affects neutrophil progenitor proliferation, differentiation, and selected end-cell functional activation (including enhanced phagocytic ability, priming of the cellular metabolism associated with respiratory burst, antibody dependent killing, and the increased expression of some functions associated with cell surface antigens).

Pharmacokinetics

Absorption and clearance of Filgrastim follows first-order pharmacokinetic modeling without apparent concentration dependence. A positive linear correlation occurred between the parenteral dose and both the serum concentration and area under the concentration-time curves. Continuous IV infusion of 20 mcg/kg of Filgrastim over 24 hours resulted in mean and median serum concentrations of approximately 48 and 56 ng/ml, respectively. Subcutaneous administration of 3.45 mcg/kg and 11.5 mcg/kg resulted in maximum serum concentrations of 4 and 49 ng/ml, respectively, within 2 to 8 hours. The volume of distribution averaged 150 ml/kg in both normal subjects and cancer patients. The elimination half-life, in both normal subjects and cancer patients, was approximately 3.5 hours. Clearance rates of Filgrastim were approximately 0.5 to 0.7 ml/minute/kg. Single parenteral doses or daily IV doses, over a 14-day period, resulted in comparable half-lives. The half-lives were similar for IV administration (231 minutes, following doses of 34.5 mcg/kg) and for SC administration (210 minutes, following Filgrastim doses of 3.45 mcg/kg). Continuous 24-hour IV infusions of 20 mcg/kg over an 11- to 20-day period produced steady-state serum concentrations of Filgrastim with no evidence of drug accumulation over the time period investigated. Pharmacokinetic data in geriatric patients (≥ 65 years) are not available.

CLINICAL INFORMATION

Indications and Uses

Cancer Patients Receiving Myelosuppressive Chemotherapy

Filgrastim is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. A complete blood count (CBC) and platelet count should be obtained prior to chemotherapy, and twice per week during Filgrastim therapy to avoid leukocytosis and to monitor the neutrophil count. In phase 3 clinical studies, Filgrastim therapy was discontinued when the Absolute Neutrophil Count (ANC) was $\geq 10,000/\text{mm}^3$ after the expected chemotherapy-induced nadir.

Patients with Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy

Filgrastim is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Cancer Patients Receiving Bone Marrow Transplant

Filgrastim is 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. It is recommended that CBCs and platelet counts be obtained at a minimum of 3 times per week following marrow infusion to monitor the recovery of marrow reconstitution.

Patients Undergoing Peripheral Blood Progenitor Cell Collection and Therapy

Filgrastim is indicated for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Mobilization allows for the collection of increased numbers of progenitor cells capable of engraftment compared with collection by leukapheresis without mobilization or bone marrow harvest. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to more rapid engraftment, which may result in a decreased need for supportive care.

Patients With Severe Chronic Neutropenia

Filgrastim is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. It is essential that serial CBCs with differential and platelet counts, and an evaluation of bone marrow morphology and karyotype be performed prior to initiation of Filgrastim therapy. The use of Filgrastim prior to confirmation of SCN may impair diagnostic efforts and may thus impair or delay evaluation and treatment of an underlying condition, other than SCN, causing the neutropenia.

Dosage and Administration

Filgrast therapy should only be given in collaboration with an oncology center which has experience in G-CSF treatment and hematology and has the necessary diagnostic facilities. The mobilization and apheresis producers should be performed in collaboration with an oncology hematology center with an acceptable experience in this field and where the monitoring of hematopoietic cells can be correctly performed.

Established cytotoxic chemotherapy

The recommended dose of Filgrast is 5mcg (0.5MU)/kg/day. The first dose of Filgrast should not be administered less than the 24 hours following cytotoxic chemotherapy. Filgrast may be given as a daily subcutaneous injection or as a daily intravenous infusion diluted in 5% glucose solution given over 30 minutes. The subcutaneous route is preferred in most cases. There is some evidence from a study of single dose administration that intravenous dosing may shorten the duration of effect. The clinical relevance of this finding to multiple dose administration is not clear. The choice of route should depend on the individual clinical circumstances.

In patient receiving cytotoxic chemotherapy, a transient increase in neutrophil counts is typically seen 1 to 2 days after initiation of Filgrast therapy. However for a sustained therapeutic response, Filgrast therapy should not discontinued before the expected nadir has passed and the neutrophil count has recovered to the normal range. Premature discontinuation of Filgrast therapy prior to the time of the expected neutrophil nadir, is not recommended.

In patient treated with myeloblastic therapy followed by bone marrow transplantation

The recommended starting dose of Filgrast is 10mcg (1.0MU)/kg/day given as a 30 minute or 24 hour

intravenous infusion or 10mcg (1.0MU)/kg/day given by continuous 24 hours subcutaneous infusion.

Filgrast should be diluted in 20ml of 5% glucose solution. The first dose of Filgrast should not be administered less than the 24 hours following cytotoxic chemotherapy but within 24 hours of bone marrow infusion. Once the neutrophil nadir has been passed, the daily dose of Filgrast should be titrated against the neutrophil response.

Peripheral Blood Progenitor Cell Collection and Therapy in Cancer Patients

The recommended dose of Filgrastim for the mobilization of PBPC is 10 mcg/kg/day SC, either as a bolus or a continuous infusion. It is recommended that Filgrastim be given for at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis. Although the optimal duration of Filgrastim administration and leukapheresis schedule have not been established, administration of Filgrastim for 6 to 7 days with leukaphereses on days 5, 6, and 7 was found to be safe and effective. Neutrophil counts should be monitored after 4 days of Filgrastim develop a WBC count $> 100,000/\text{mm}^3$. In all clinical trials of Filgrastim for the mobilization of PBPC, Filgrastim was also administered after reinfusion of the collected cells.

Patients With Severe Chronic Neutropenia

Filgrastim should be administered to those patients in whom a diagnosis of congenital, cyclic, or idiopathic neutropenia has been definitively confirmed. Other diseases associated with neutropenia should be ruled out.

Starting Dose

Congenital Neutropenia

The recommended daily starting dose is 6 mcg/kg/day BID SC.

Idiopathic or Cyclic Neutropenia

The recommended daily starting dose is 5 mcg/kg/day as a single SC injection.

Dose Adjustments

Chronic daily administration is required to maintain clinical benefit. Absolute neutrophil count should not be used as the sole indication of efficacy. The dose should be individually adjusted based on the patients' clinical course as well as ANC. In the SCN postmarketing surveillance study, the reported median daily doses of Filgrastim were: 6.0 mcg/kg (congenital neutropenia), 2.1 mcg/kg (cyclic neutropenia) and 1.2 mcg/kg (idiopathic neutropenia). In rare instances, patients with congenital neutropenia have required doses of Filgrastim ≥ 100 mcg/kg/day.

HIV infection

For reversal of neutropenia

The recommended starting dose of Filgrast is 1mcg (0.1MU)/kg/day is given daily by subcutaneous injection with titration up to a maximum of 4 mcg (0.4MU) /kg/day until a normal neutrophil count is reached can be maintained (ANC $> 2.0 \times 10^9/\text{l}$) In clinical studies, $>90\%$ of patients responded at these doses, achieving reversal of neutropenia in a median of 2 days.

In small number of patients ($<10\%$), Doses up to 10 mcg (1.0MU)/kg/day were required to achieve reversal of neutropenia.

Special Dosage Instructions

Clinical trials with Filgrast have included a small number of elderly patients but special studies have not performed in this group and therefore specific dosage recommendations have not been made. The dosage recommendations in pediatric are the same as those in adults receiving myelosuppressive cytotoxic chemotherapy. Studies of Filgrast in patients with severe impairment of renal or hepatic function demonstrate that it exhibits a similar pharmacokinetics and pharmacodynamics profile to that seen in normal individual.

Dilution

If required, Filgrastim may be diluted in 5% dextrose. Filgrastim diluted to concentrations between 5 and 15 mcg/mL should be protected from adsorption to plastic materials by the addition of Albumin (Human) to a final concentration of 2 mg/ml. When diluted in 5% dextrose or 5% dextrose plus Albumin (Human), Filgrastim is compatible with glass bottles, PVC and polyolefin IV bags, and polypropylene syringes. Dilution of Filgrastim to a final concentration of less than 5 mcg/ml is not recommended at any time. Do not dilute with saline at any time; product may precipitate.

Side Effects

Allergic Reactions

Allergic-type reactions occurring on initial or subsequent treatment have been reported in < 1 in 4000 patients treated with Filgrastim. These have generally been characterized by systemic symptoms involving at least 2 body systems, most often skin (rash, urticaria, facial edema), respiratory (wheezing, dyspnea), and cardiovascular (hypotension, tachycardia). Some reactions occurred on initial exposure. Reactions tended to occur within the first 30 minutes after administration and appeared to occur more frequently in patients receiving Filgrastim IV. Rapid resolution of symptoms occurred in most cases after administration of antihistamines, steroids, bronchodilators and/or epinephrine. Symptoms recurred in more than half the patients who were rechallenged.

Splenic Rupture

Splenic rupture, including fatal cases, has been reported following the administration of Filgrastim. Individuals receiving Filgrastim who report left upper abdominal and/or shoulder tip pain should be evaluated for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) has been reported in patients receiving Filgrastim, and is postulated to be secondary to an influx of neutrophils to sites of inflammation in the lungs. Patients receiving Filgrastim who develop fever, lung infiltrates, or respiratory distress should be evaluated for the possibility of ARDS. In the event that ARDS occurs, Filgrastim should be withheld until resolution of ARDS or discontinued. Patients should receive appropriate medical management for this condition.

Alveolar Hemorrhage and Hemoptysis

Alveolar hemorrhage manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization has been reported in healthy donors undergoing peripheral blood progenitor cell (PBPC) mobilization. Hemoptysis resolved with discontinuation of Filgrastim. The use of Filgrastim for PBPC mobilization in healthy donors is not an approved indication.

Sickle Cell Disorders

Severe sickle cell crises, in some cases resulting in death, have been associated with the use of Filgrastim in patients with sickle cell disorders. Only physicians qualified by specialized training or experience in the treatment of patients with sickle cell disorders should prescribe Filgrastim for such patients, and only after careful consideration of the potential risks and benefits.

Patients with Severe Chronic Neutropenia

The safety and efficacy of Filgrastim in the treatment of neutropenia due to other hematopoietic disorders (eg, myelodysplastic syndrome [MDS]) have not been established. Care should be taken to confirm the diagnosis of SCN before initiating Filgrastim therapy.

MDS and AML have been reported to occur in the natural history of congenital neutropenia without cytokine therapy. Cytogenetic abnormalities, transformation to MDS, and AML have also been observed in patients treated with Filgrast for SCN. Based on available data including a postmarketing surveillance study, the risk of developing MDS and AML appears to be confined to the subset of patients

with congenital neutropenia. Abnormal cytogenetics and MDS have been associated with the eventual development of myeloid leukemia. The effect of Filgrastim on the development of abnormal cytogenetics and the effect of continued Filgrastim administration in patients with abnormal cytogenetics or MDS are unknown. If a patient with SCN develops abnormal cytogenetics or myelodysplasia, the risks and benefits of continuing Filgrastim should be carefully considered.

Precautions

Simultaneous Use with Chemotherapy and Radiation Therapy

The safety and efficacy of Filgrastim given simultaneously with cytotoxic chemotherapy have not been established. Because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, do not use Filgrastim in the period 24 hours before through 24 hours after the administration of cytotoxic chemotherapy.

The efficacy of Filgrastim has not been evaluated in patients receiving chemotherapy associated with delayed myelosuppression (eg, nitrosoureas) or with mitomycin C or with myelosuppressive doses of antimetabolites such as 5-fluorouracil.

The safety and efficacy of Filgrastim have not been evaluated in patients receiving concurrent radiation therapy. Simultaneous use of Filgrastim with chemotherapy and radiation therapy should be avoided.

Potential Effect on Malignant Cells

Filgrastim is a growth factor that primarily stimulates neutrophils. However, the possibility that Filgrastim can act as a growth factor for any tumor type cannot be excluded. In a randomized study evaluating the effects of Filgrastim versus placebo in patients undergoing remission induction for AML, there was no significant difference in remission rate, disease-free, or overall survival.

The safety of Filgrastim in chronic myeloid leukemia (CML) and myelodysplasia has not been established

When Filgrastim is used to mobilize PBPC, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of reinfusion of tumor cells has not been well studied, and the limited data available are inconclusive.

Information for Patients and Caregivers

Patients should be referred to the "Information for Patients and Caregivers" labeling included with the package insert in each dispensing pack of Filgrastim vials or Filgrastim prefilled syringes. The "Information for Patients and Caregivers" labeling provides information about neutrophils and neutropenia and the safety and efficacy of Filgrastim. It is not intended to be a disclosure of all known or possible effects.

Patients with Severe Chronic Neutropenia

During the initial 4 weeks of Filgrastim therapy and during the 2 weeks following any dose adjustment, a CBC with differential and platelet count should be performed twice weekly. Once a patient is clinically stable, a CBC with differential and platelet count should be performed monthly during the first year of treatment. Thereafter, if clinically stable, routine monitoring with regular CBCs (ie, as clinically indicated but at least quarterly) is recommended. Additionally, for those patients with congenital neutropenia, annual bone marrow and cytogenetic evaluations should be performed throughout the duration of treatment.

Drug Interaction

Drug interactions between Filgrastim and other drugs have not been fully evaluated. Drugs which may potentiate the release of neutrophils, such as lithium, should be used with caution.

Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of Filgrastim has not been studied. Filgrastim failed to induce bacterial gene mutations in either the presence or absence of a drug metabolizing enzyme system. Filgrastim had no observed effect on the fertility of male or female rats, or on gestation at doses up to 500 mcg/kg.

Pregnancy Category C

Filgrastim has been shown to have adverse effects in pregnant rabbits when given in doses 2 to 10 times the human dose. Since there are no adequate and well-controlled studies in pregnant women, the effect, if any, of Filgrastim on the developing fetus or the reproductive capacity of the mother is unknown. However, the scientific literature describes transplacental passage of Filgrastim when administered to pregnant rats during the latter part of gestation and apparent transplacental passage of Filgrastim when administered to pregnant humans by ≥ 30 hours prior to preterm delivery (≥ 30 weeks gestation). Filgrastim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In rabbits, increased abortion and embryolethality were observed in animals treated with Filgrastim at 80 mcg/kg/day. Filgrastim administered to pregnant rabbits at doses of 80 mcg/kg/day during the period of organogenesis was associated with increased fetal resorption, genitourinary bleeding, developmental abnormalities, decreased body weight, live births, and food consumption. External abnormalities were not observed in the fetuses of dams treated at 80 mcg/kg/day. Reproductive studies in pregnant rats have shown that Filgrastim was not associated with lethal, teratogenic, or behavioral effects on fetuses when administered by daily IV injection during the period of organogenesis at dose levels up to 575 mcg/kg/day.

In Segment III studies in rats, offspring of dams treated at > 20 mcg/kg/day exhibited a delay in external differentiation (detachment of auricles and descent of testes) and slight growth retardation, possibly due to lower body weight of females during rearing and nursing. Offspring of dams treated at 100 mcg/kg/day exhibited decreased body weights at birth, and a slightly reduced 4-day survival rate.

Nursing Mothers

It is not known whether Filgrastim is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if Filgrastim is administered to a nursing woman.

Pediatric Use

In a phase 3 study to assess the safety and efficacy of Filgrastim in the treatment of SCN, 120 patients with a median age of 12 years were studied. Of the 120 patients, 12 were infants (1 month to 2 years of age), 47 were children (2 to 12 years of age), and 9 were adolescents (12 to 16 years of age). Additional information is available from a SCN postmarketing surveillance study, which includes long-term follow-up of patients in the clinical studies and information from additional patients who entered directly into the postmarketing surveillance study. Of the 531 patients in the surveillance study as of 31 December 1997, 32 were infants, 200 were children, and 68 were adolescents.

Pediatric patients with congenital types of neutropenia (Kostmann's syndrome, congenital agranulocytosis, or Schwachman-Diamond syndrome) have developed cytogenetic abnormalities and have undergone transformation to MDS and AML while receiving chronic Filgrastim treatment. The relationship of these events to Filgrastim administration is unknown.

Long-term follow-up data from the postmarketing surveillance study suggest that height and weight are not adversely affected in patients who received up to 5 years of Filgrastim treatment. Limited data from patients who were followed in the phase 3 study for 1.5 years did not suggest alterations in sexual maturation or endocrine function.

The safety and efficacy in neonates and patients with autoimmune neutropenia of infancy have not been established.

In the cancer setting, 12 pediatric patients with

neuroblastoma have received up to 6 cycles of cyclophosphamide, cisplatin, doxorubicin, and etoposide chemotherapy concurrently with Filgrastim; in this population, Filgrastim was well tolerated. There was one report of palpable splenomegaly associated with Filgrastim therapy; however, the only consistently reported adverse event was musculoskeletal pain, which is no different from the experience in the adult population.

Adverse Reactions

Patients with Acute Myeloid Leukemia

In a randomized phase 3 clinical trial, 259 patients received Filgrastim and 262 patients received placebo post chemotherapy. Overall, the frequency of all reported adverse events was similar in both the Filgrastim and placebo groups (83% vs 82% in Induction 1; 61% vs 64% in Consolidation 1). Adverse events reported more frequently in the Filgrastim-treated group included: petechiae (17% vs 14%), epistaxis (9% vs 5%), and transfusion reactions (10% vs 5%). There were no significant differences in the frequency of these events.

There were a similar number of deaths in each treatment group during induction (25 Filgrastim vs 27 placebo). The primary causes of death included infection (9 vs 18), persistent leukemia (7 vs 5), and hemorrhage (6 vs 3). Of the hemorrhagic deaths, 5 cerebral hemorrhages were reported in the Filgrastim group and 1 in the placebo group. Other serious nonfatal hemorrhagic events were reported in the respiratory tract (4 vs 1), skin (4 vs 4), gastrointestinal tract (2 vs 2), urinary tract (1 vs 1), ocular (1 vs 0), and other nonspecific sites (2 vs 1). While 19 (7%) patients in the Filgrastim group and 5 (2%) patients in the placebo group experienced severe or fatal hemorrhagic events, overall, hemorrhagic adverse events were reported at a similar frequency in both groups (40% vs 38%). The time to transfusion-independent platelet recovery and the number of days of platelet transfusions were similar in both groups.

Cancer Patients Receiving Bone Marrow Transplantation

In clinical trials, the reported adverse effects were those typically seen in patients receiving intensive chemotherapy followed by bone marrow transplant (BMT). The most common events reported in both control and treatment groups included stomatitis, nausea and vomiting, generally of mild-to-moderate severity and were considered unrelated to Filgrastim. In the randomized studies of BMT involving 167 patients who received study drug, the following events occurred more frequently in patients treated with Filgrastim than in controls: nausea (10% vs 4%), vomiting (7% vs 3%), hypertension (4% vs 0%), rash (12% vs 10%) and peritonitis (2% vs 0%). None of these events were reported by the investigator to be related to Filgrastim. One event of erythema nodosum was reported moderate in severity and possibly related to Filgrastim.

Generally, adverse events observed in nonrandomized studies were similar to those seen in randomized studies, occurred in a minority of patients, and were of mild-to-moderate severity. In one study (n = 45), 3 serious adverse events reported by the investigator were considered possibly related to Filgrastim. These included 2 events of renal insufficiency and 1 event of capillary leak syndrome. The relationship of these events to Filgrastim remains unclear since they occurred in patients with culture-proven infection with clinical sepsis who were receiving potentially nephrotoxic antibacterial and antifungal therapy.

Cancer Patients Undergoing Peripheral Blood Progenitor Cell Collection and Therapy

In clinical trials, 126 patients received Filgrastim for PBPC mobilization. In this setting, Filgrastim was generally well tolerated. Adverse events related to Filgrastim consisted primarily of mild-to-moderate musculoskeletal symptoms, reported in 44% of patients. These symptoms were predominantly events of medullary bone pain (33%). Headache was reported related to Filgrastim in 7% of patients. Transient increases in alkaline phosphatase related to Filgrastim were reported in 21% of the patients who had serum chemistries measured; most were mild-to-moderate.

All patients had increases in neutrophil counts during mobilization, consistent with the biological effects of Filgrastim. Two patients had a WBC count $\geq 100,000/\text{mm}^3$. No sequelae were associated with any grade of leukocytosis.

Sixty-five percent of patients had mild-to-moderate anemia and 97% of patients had decreases in platelet counts; 5 patients (out of 126) had decreased platelet counts to $< 50,000/\text{mm}^3$. Anemia & thrombocytopenia have been reported to be related to leukapheresis; however, the possibility that Filgrastim mobilization may contribute to anemia or thrombocytopenia has not been ruled out.

Overdosage

In cancer patients receiving Filgrastim as an adjunct to myelosuppressive chemotherapy, it is recommended, to avoid the potential risks of excessive leukocytosis, that Filgrastim therapy be discontinued if the ANC surpasses $10,000/\text{mm}^3$ after the chemotherapy-induced ANC nadir has occurred. Doses of Filgrastim that increase the ANC beyond $10,000/\text{mm}^3$ may not result in any additional clinical benefit.

The maximum tolerated dose of Filgrastim has not been determined. Efficacy was demonstrated at doses of 4 to 8 mcg/kg/day in the phase 3 study of nonmyeloablative chemotherapy. Patients in the BMT studies received up to 138 mcg/kg/day without toxic effects, although there was a flattening of the dose response curve above daily doses of greater than 10 mcg/kg/day.

In Filgrastim clinical trials of cancer patients receiving myelosuppressive chemotherapy, WBC counts $\geq 100,000/\text{mm}^3$ have been reported in less than 5% of patients, but were not associated with any reported adverse clinical effects.

In cancer patients receiving myelosuppressive chemotherapy, discontinuation of Filgrastim therapy usually results in a 50% decrease in circulating neutrophils within 1 to 2 days, with a return to pretreatment levels in 1 to 7 days.

Contraindications

Filgrastim is contraindicated in patients with known hypersensitivity to *E.coli*-derived proteins, Filgrastim or any component of the product.

PHARMACEUTICAL INFORMATION

Storage Conditions

Filgrastim should be stored in the refrigerator at 2° to 8°C (36° to 46°F). Avoid shaking. Prior to injection, Filgrastim may be allowed to reach room temperature for a maximum of 24 hours. Any prefilled syringe left at room temperature for greater than 24 hours should be discarded.

Presentation & Packaging

Each box contains one Pre-filled syringe containing Filgrastim INN 300 mcg (30MU).

