Neufil®

Filgrastim BP

Presentation

Neufil® 120 mcg injection: Each pre-filled syringe contains 0.2 ml sterile solution of Filgrastim BP 120 mcg.

Neufil® 30 MU injection: Each pre-filled syringe contains 0.5 ml sterile solution of Filgrastim BP 30 MU (300 micrograms).

Description

Filgrastim is a Granulocyte Colony-Stimulating Factor (G-CSF), produced by recombinant DNA technology. G-CSF is a glycoprotein which regulates the production and release of functional neutrophils from the bone marrow. Filgrastim causes marked increase in peripheral blood neutrophil counts within 24 hours, with minor increases in monocytes. In some severe chronic neutropenia patients, Filgrastim can also induce a minor increase in the number of circulating eosinophils and basophils relative to baseline; some of these patients may present with eosinophilia or basophilia already prior to the treatment.

Indication

Filgrastim is indicated for -

- The reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy.
- The reduction of neutropenia and its clinical sequelae in patients undergoing myeloablative therapy followed by bone marrow transplantation.
- Mobilization of peripheral blood progenitor cells (PBPC) in normal donors.
- In patients, children or adults, with severe congenital, cyclic or idiopathic neutropenia with an Absolute Neutrophil Count (ANC) 0.5 x 10^9/L.
- The treatment of persistent neutropenia (ANC 1 x 10^9/L) in patients with advanced HIV infection.

Dosage and Administration

Filgrastim is given by subcutaneous injection or intravenous infusion. Filgrastim 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.

Established cytotoxic chemotherapy:

The recommended dose of Filgrastim is 0.5 MU (5 micrograms)/kg/day. The first dose of Filgrastim should not be administered less than 24 hours following cytotoxic chemotherapy. Filgrastim may be given as a daily subcutaneous injection or as a daily intravenous infusion diluted in 5% glucose solution given over 30 minutes.

Daily dosing with Filgrastim should continue until the expected neutrophil nadir is passed and the neutrophil count has recovered to the normal range. Following established chemotherapy with solid tumors, lymphomas, and lymphoid leukemia, it is expected that the duration of treatment required to fulfill this criteria will be up to 14 days. Following induction and consolidation treatment for acute myeloid leukemia, the duration of treatment may be substantially longer (up to 38 days) depending on the type, dose and schedule of cytotoxic chemotherapy used.

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

Severe chronic neutropenia (SCN):

Congenital neutropenia: The recommended starting dose is 1.2 MU (12 micrograms)/kg/day subcutaneously as a single dose or in divided doses.

Idiopathic or cyclic neutropenia: The recommended starting dose is 0.5 MU (5 micrograms)/kg/day subcutaneously as a single dose or in divided doses.

Dose adjustment: Filgrastim should be administered daily by subcutaneous injection until the neutrophil count has reached and can be maintained at more than 1.5 x 10^9/L. When the response has been obtained the minimal effective dose to maintain this level should be established. Long term daily administration is required to maintain an adequate neutrophil count. After one to two weeks of therapy, the initial dose may be doubled or halved depending upon the patient's response. Subsequently the dose may be individually adjusted every 1 to 2 weeks to maintain the average neutrophil count between 1.5 x10^9/L and 10 x10^9/L. A faster schedule of dose escalation may be considered in patients presenting with severe infections.

In clinical trials, 97% of patients who responded had a complete response at doses 24 micrograms/kg/day in patients with severe chronic neutropenia has not been established.

The safety and efficacy of Filgrastim are similar in adults and children receiving cytotoxic chemotherapy.

Special Dosage Instructions

Clinical trials with Filgrastim have included a small number of elderly patients but special studies have not been performed in this group and therefore specific dosage recommendations cannot be made.

Studies of Filgrastim in patients with severe impairment of renal or hepatic function demonstrate that it exhibits a similar pharmacokinetic and pharmacodynamic profile to that seen in normal individuals. Dose adjustment is not required in these circumstances.

Adverse Reactions

Nausea, vomiting, musculoskeletal pain, bone pain, myalgia, headache, exacerbation of rheumatoid arthritis, splenic rupture, sickle cell crisis, acute respiratory distress syndrome (ARDS), increased alkaline phosphatase.

Contraindications

Filgrastim should not be administered in patients with known hypersensitivity to Filgrastim or to any of the excipients.

Filgrastim should not be used to increase the dose of cytotoxic chemotherapy beyond established dosage regimens.

Filgrastim should not be administered to patients with severe congenital neutropenia (Kostmann's syndrome) with abnormal cytogenetics.

Precautions

- Because of the potential sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, Filgrastim should not be administered 24 hours before to 24 hours after the administration of cytotoxic chemotherapy.
- Special caution should be used when treating patients with high-dose chemotherapy, because improved tumor outcome has not been demonstrated, and intensified doses of chemotherapeutic agents may lead to increased toxicities including cardiac, pulmonary, neurological and dermatological effects.
- Regular monitoring of complete blood count is recommended twice per week during the therapy.
- Filgrastim is given by subcutaneous injection or intravenous infusion.
- Monitoring of bone density may be indicated in patients with underlying osteoporotic bone diseases who undergo continuous therapy with Filgrastim for more than six months.

Pregnancy

The safety of Filgrastim has not been established in pregnant women. In pregnancy, the possible risk of Filgrastim use to the fetus must be weighed against the expected therapeutic benefit.

Nursing Mothers

It is not known whether Filgrastim is excreted in human milk. Filgrastim is not recommended for use in nursing mother.

Pediatric use

Established cytotoxic chemotherapy

The safety and efficacy of Filgrastim are similar in adults and children receiving cytotoxic chemotherapy

In patients with severe chronic neutropenia (SCN)

The safety and efficacy in neonates have not been established.

Drug Interactions

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.

Overdose

The effects of Filgrastim overdose have not been established. Doses up to 138 micrograms/kg/day were administered to patients in BMT studies without toxic effects. Discontinuation of Filgrastim therapy usually results in a 50% decrease in circulating neutrophils within one to two days, with a return to normal levels in one to seven days.

Commercial pack

Neufil® 120 mcg pre-filled syringe injection: Each box contains 1 pre-filled syringe containing 0.2 ml sterile solution of Filgrastim BP 120 mcg and an alcohol pad.

Neufil® 30 MU pre-filled syringe injection: Each box contains 1 pre-filled syringe containing 0.5 ml sterile solution of Filgrastim BP 30 MU (300 micrograms) and an alcohol pad.

Storage

- Filgrastim should be stored in a refrigerator at 2-8 °C.
- Do not freeze.
- Do not shake.
- Keep away from light.

Medicine: Keep out of reach of children

For further information, please contact: 01977 157 108
(9.00 am - 5.00 pm)

Healthcare

Manufactured by
Healthcare Pharmaceuticals Ltd.
Rajendrapur, Gazipur, Bangladesh

HP 52232/1