Neupomax

Filgrastim BP

Composition

Neupomax 30 MU injection: Each pre-filled syringe contains Filgrastim BP 30 MU (300 mcg) in 0.5 ml solution

Pharmacology

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 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 & Administration

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.

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.

Warning & 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.

Side effects

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.

Use in Special Population

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.

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.

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.

Storage

- Filgrastim should be stored in a refrigerator at 2^0 C-8^0 C
- Do not freeze.
- Do not shake.
- Keep away from light.

Medicine: Keep out of the reach of children

Packing

Neupomax 30 MU Injection: Each box contains 1 pre-filled syringe of 0.5 ml solution of Filgrastim BP 30 MU (300 mcg) injection and an alcohol pad.

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Manufactured by

ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**
Kaliakoir, Gazipur, Bangladesh

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