Filastin® 30

Filgrastim 30 MU

Presentation

Filastin® 30 pre-filled syringe injection**:** Each pre-filled syringe contains 0.5 ml sterile solution which contains Filgrastim (G-CSF) 300 microgram (30 MU) as Filgrastim concentrated solution EP.

Description

Filgrastim is a human granulocyte colony stimulating factor (G-CSF) produced by recombinant DNA technology. G-CSF regulates the production of neutrophils within the bone marrow and affects neutrophil progenitor proliferation, differentiation and enhances phagocytic activity.

Indications and uses

- Cancer patients receiving myelosuppressive chemotherapy
- Patients with Acute Myeloid Leukemia receiving induction or consolidation chemotherapy
- Cancer patients receiving bone marrow transplant
- Patients with severe neutropenia
- Peripheral blood progenitor cell collection and therapy

Dosage guideline

- Cancer patients receiving myelosuppressive chemotherapy: The recommended starting dose of Filgrastim is 5 mcg/kg/day. Doses may be increased in increments of 5 mcg/kg for each chemotherapy cycle
- Cancer patients receiving bone marrow transplant: The recommended dose of Filgrastim following bone marrow transplantation is 10 mcg/kg/day. During the period of neutrophil recovery, the daily dose should be titrated against the neutrophil response as follows:

Absolute Neutrophil Count (ANC)	Dose adjustment
ANC>1000/mm^3 for consecutive 3 days	Reduces to 5 mcg/kg/day
If ANC remains >1000/mm^3 for consecutive 3 days	Discontinue drug
If ANC remains <1000/mm^3 for consecutive 3 days	Resume at 5 mcg/kg/day

- Patients with chronic neutropenia: The recommended daily starting dose is 5 mcg/kg/day in idiopathic neutropenia
- Peripheral blood progenitor cell collection and therapy: The recommended starting dose is 10 mcg/kg/day. Dose may be adjusted as required

Side-effects

- Splenic rupture
- Acute Respiratory Distress Syndrome
- Alveolar hemorrhage and haemoptysis
- Sickle cell crisis

Contraindications

Hypersensitivity to *E. coli* derived proteins, Filgrastim or any component of the product.

Precautions

- Filgrastim should not be administered within 24 hours before and after chemotherapy
- The possibility of Filgrastim acting as a growth factor for any tumor type cannot be excluded
- To avoid adverse effects of excessive neutrophils complete blood count is recommended twice per week during treatment
- Filgrastim is given by subcutaneous or intravenous infusion as required
- Dilution of Filgrastim conc less than 5 mcg/ml is not recommended at any time
- Filgrastim may be diluted in 5% dextrose as required

Pregnancy and Lactation (Pregnancy Category C)

There are no adequate and well controlled trial on pregnant women, the effect of Filgrastim on the developing fetus and mother is unknown.

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.

Overdosage

The possibility of Filgrastim acting as a growth factor for any tumor type and adverse effects of excessive neutrophils may occur in overdose of Filgrastim.

Storage

Filgrastim should be stored at 2 °C to 8 °C in a refrigerator and shaking should be avoided. If particulates or discoloration are observed, the container should not be used.

Commercial pack

Filastin® 30 pre-filled syringe injection: Each pre-filled syringe contains 0.5 ml sterile solution which contains Filgrastim (G-CSF) 300 microgram (30 MU).

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

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