Pegfilgrastim

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Drug name: Pegfilgrastim also is known as Neulasta® (Amgen Inc., Thousand Oaks, CA).

Classification: Pegfilgrastim is a pegylated form of the colony-stimulating factor filgrastim. The prefix "peg" refers to the polyethylene unit that is added to filgrastim to make it a larger molecule. Enlarging the protein enables it to stay in the body longer, allowing for a single dose per chemotherapy cycle.

Action: Pegfilgrastim binds to specific surface receptors on hematopoietic cells and stimulates the proliferation, differentiation, and commitment of these cells. Pegfilgrastim has the same mechanism of action as filgrastim.

Indication: Pegfilgrastim is indicated for patients with nonmyeloid malignancies receiving myelosuppressive anticancer medications to reduce the incidence of febrile neutropenia and infection.

Metabolism: Pegfilgrastim has prolonged persistence in vivo as compared to filgrastim. Serum clearance of pegfilgrastim is directly related to the number of neutrophils. As neutrophil levels return to normal, the serum concentration of pegfilgrastim decreases.

Excretion: Pegfilgrastim has a reduced renal clearance as compared to filgrastim.

Half-life: Because it is a pegylated molecule, pegfilgrastim has a longer serum half-life than filgrastim. The half-life of pegfilgrastim is 15–80 hours, as compared to 3.5 hours for filgrastim.

Effect on blood counts: Pegfilgrastim and filgrastim are given to decrease neutropenia in patients receiving myelosuppressive anticancer medications. Complete blood counts and platelet counts should be monitored closely in all patients receiving myelosuppressive chemotherapy.

Pegfilgrastim was evaluated in two randomized, double-blind, active control studies of patients with breast cancer receiving doxorubicin 60 mg/m^2 and docetaxel 75 mg/m^2. The studies compared a single dose of pegfilgrastim to daily doses of filgrastim. Both studies concluded that the mean days of severe neutropenia (grade 4) in the patients receiving pegfilgrastim (1.8 days and 1.7 days) did not exceed that of the filgrastim-treated patients (1.6 days) by more than one day. Chemotherapy regimens similar to the one used in this study have been reported to have a mean duration of five to seven days of severe neutropenia. These studies found that a single dose of pegfilgrastim is as effective as daily doses of filgrastim and has the potential to simplify the management of neutropenia in patients receiving chemotherapy.

Adverse reactions and effects: The most common adverse reaction to pegfilgrastim during clinical trials was medullary bone pain, which generally was reported as mild to moderate in severity. The incidence of bone pain was 26%, which is comparable to that reported by patients receiving filgrastim. The only serious event not attributed to underlying or concurrent disease was one case of hypoxia. Also noted were reversible elevations of lactic dehydrogenase, alkaline phosphates, and uric acid that did not require treatment. Allergic-type reactions were not observed in clinical trials of pegfilgrastim but have been reported in patients receiving filgrastim. Pegfilgrastim has not been studied in patients for stem cell mobilization and is not indicated for that use. Concern in this setting is the rare incidence of splenic rupture, which has been reported with the use of filgrastim in the mobilization of healthy donors and patients for stem cell transplant. Patients who report upper-left abdominal or shoulder pain should be evaluated for enlarged spleen or splenic rupture. Adult respiratory distress syndrome (ARDS) should be considered in neutropenic patients who develop fever, lung infiltrates, or respiratory distress. ARDS has been reported in patients who have received filgrastim and is believed to be secondary to the influx of neutrophils to sites of inflammation in the lungs. In rare cases, patients with sickle cell disease who have received filgrastim have developed severe sickle cell crisis. If pegfilgrastim is used in patients with sickle cell disease, they should be well hydrated and monitored closely.

Route: Pegfilgrastim is administered as a subcutaneous (SC) injection.

Dosage and administration: The recommended dosage of pegfilgrastim is 6 mg SC once per chemotherapy cycle. It is not administered 14 days before or 24 hours after chemotherapy administration. Before administration, inspect pegfilgrastim for particulate matter and discoloration and do not administer the drug if either is observed. This drug is not recommended for infants, children, or adolescents who weigh less than 100 lbs (45 kg). After administration of the drug, the needle guard on the prefilled syringe

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