Pegneufil®

Pegfilgrastim INN

Presentation

Pegneufil® 6 mg injection: Each pre-filled syringe contains 0.6 ml sterile solution of Pegfilgrastim INN 6 mg.

Description

Pegfilgrastim, a Granulocyte Colony-Stimulating Factor (G-CSF) is a pegylated glycoprotein which regulates the production and release of functional neutrophils from bone marrow. Pegfilgrastim is a covalent conjugate of recombinant methionyl human G-CSF (Filgrastim) and monomethoxy polyethylene glycol. Filgrastim is a water-soluble 175 amino acid protein with a molecular weight of approximately 19 kilodaltons (kD) and a 20 kD monomethoxy polyethylene glycol molecule is covalently bound to the N-terminal methionyl residue of filgrastim. The average molecular weight of pegfilgrastim is approximately 39 kD.

Indication

Pegfilgrastim is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Dosage and administration

The recommended dosage of Pegfilgrastim is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle in adults. Do not administer Pegfilgrastim between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer Pegfilgrastim if discoloration or particulates are observed.

NOTE: The needle cover on the single-use pre-filled syringe contains dry natural rubber (latex); persons with latex allergies should not administer this product.

Contraindications

Do not administer Pegfilgrastim to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Warnings and precautions

- Fatal splenic rupture can occur. Evaluate for splenomegaly or splenic rupture in patients with left upper abdominal or shoulder pain.
- Acute Respiratory Distress Syndrome (ARDS) can occur. Evaluate for ARDS in patients who develop fever, lung infiltrates, or respiratory distress. Discontinue Pegfilgrastim in patients with ARDS.
- Serious allergic reactions, including anaphylaxis, can occur. Permanently discontinue Pegfilgrastim in patients with serious allergic reactions.

Adverse reactions

Splenic Rupture

Splenic rupture, including fatal cases, can occur following the administration of Pegfilgrastim. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Pegfilgrastim.

Acute Respiratory Distress Syndrome

Acute Respiratory Distress Syndrome (ARDS) can occur in patients receiving Pegfilgrastim. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Pegfilgrastim for ARDS. Discontinue Pegfilgrastim in patients with ARDS.

Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis can occur in patients receiving Pegfilgrastim. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Pegfilgrastim in patients with serious allergic reactions. Do not administer Pegfilgrastim to patients with a history of serious allergic reactions to Pegfilgrastim or Filgrastim.

Patients with Sickle Cell Disorders

Severe sickle cell crises can occur in patients with sickle cell disorders receiving Pegfilgrastim. Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving Filgrastim, the parent compound of Pegfilgrastim.

Use in specific populations

Pregnancy: Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Pegfilgrastim was embryo toxic and increased pregnancy loss in pregnant rabbits that received cumulative doses approximately 4 times the recommended human dose (based on body surface area). Signs of maternal toxicity occurred at these doses. Pegfilgrastim should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Pegfilgrastim is secreted in human milk. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates. Caution should be exercised when administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Pegfilgrastim in pediatric patients have not been established.

Geriatric Use

Of the 932 patients with cancer who received Pegfilgrastim in clinical studies, 139 (15%) were age 65 and over, and 18 (2%) were age 75 and over. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

Renal Impairment

In a study of 30 subjects with varying degrees of renal dysfunction, including end stage renal disease, renal dysfunction had no effect on the pharmacokinetics of Pegfilgrastim. Therefore, Pegfilgrastim dose adjustment in patients with renal dysfunction is not necessary.

Drug Interaction

No formal drug interaction studies between Pegfilgrastim and other drugs have been performed. Increased hematopoietic activity of the bone marrow in response to growth factor therapy may result in transiently positive bone-imaging changes. Consider these findings when interpreting bone-imaging results. This medicinal product must not be mixed with other medicinal product, particularly sodium chloride solutions.

Overdose

The maximum amount of Pegfilgrastim that can be safely administered in single or multiple doses has not been determined. Single subcutaneous doses of 300 mcg/kg have been administered to 8 healthy volunteers and 3 patients with non-small cell lung cancer without serious adverse effects. These patients experienced a mean maximum Absolute Neutrophil Count (ANC) of 55 x 10^9/L, with a corresponding mean maximum WBC of 67 x 10^9/L. The absolute maximum ANC observed was 96 x 10^9/L with a corresponding absolute maximum WBC observed of 120 x 10^9/L.

Storage

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

Commercial pack

Pegneufil® 6 mg injection: Each box contains 1 pre-filled syringe containig 0.6 ml sterile solution of Pegfilgrastim INN 6 mg and an alcohol pad.

Medicine: Keep out of reach of children

For further information, please contact: 01977 158 926
(9.00 am - 5.00 pm)

Healthcare

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