Pegfilgrast

Pegfilgrastim INN

pre-filled syringe contains 0.6 mL solution containing Pegfilgrastim INN 6 mg.

mulating factor that acts on hematopoietic cells by binding to specific cell stimulating proliferation, differentiation, commitment and end cell functional

gfilgrastim were studied in 379 patients with cancer. The pharmacokinetics of and clearance decreased with increases in dose. Neutrophil receptor binding f the clearance of Pegfilgrastim, and serum clearance is directly related to the addition to numbers of neutrophils, body weight appeared to be a factor. eights experienced higher systemic exposure to Pegfilgrastim after receiving a weight. A large variability in the pharmacokinetics of Pegfilgrastim was gfilgrastim ranged from 15 to 80 hours after subcutaneous injection.

s were observed in the pharmacokinetics of Pegfilgrastim, and no differences macokinetics of geriatric patients (≥65 years of age) compared with younger The pharmacokinetics of Pegfilgrastim were studied in pediatric patients with had no effect on the pharmacokinetics of Pegfilgrastim. The pharmacokinetic c insufficiency has not been assessed.

decrease the incidence of infection, as manifested by febrile neutropenia, in malignancies receiving myelosuppressive anti-cancer drugs associated with a e of febrile neutropenia.

d for the mobilization of peripheral blood progenitor cells for hematopoietic

ATION

of Pegfilgrastim is a single subcutaneous injection of 6 mg administered once adults. Do not administer Pegfilgrastim between 14 days before and 24 hours xic chemotherapy.

drug products for particulate matter and discoloration prior to administration, ainer permit. Do not administer Pegfilgrastim if discoloration or particulates are

the single-use pre-filled syringe contains dry natural rubber (latex); persons ot administer this product.

stim to patients with a history of serious allergic reactions to Pegfilgrastim or

ith varying degrees of renal dysfunction, including end stage renal disease, fect on the pharmacokinetics of Pegfilgrastim. Therefore, Pegfilgrastim dose enal dysfunction is not necessary

ns, there is a potential for immunogenicity. Binding antibodies to Pegfilgrastim core assay. The approximate limit of detection for this assay is 500 ng/mL. ies were detected in approximately 6% (51/849) of patients with metastatic Pegfilgrastim-treated subjects who were negative at baseline developed lgrastim following treatment. None of these 4 patients had evidence of ted using a cell-based bioassay.

rmation is highly dependent on the sensitivity and specificity of the assay and ntibody positivity in an assay may be influenced by several factors, including le handling, timing of sample collection, concomitant medications and e reasons, comparison of the incidence of antibodies to Pegfilgrastim with the her products may be misleading.

tal cases, can occur following the administration of Pegfilgrastim. Evaluate for ic rupture in patients who report left upper abdominal or shoulder pain after

s Syndrome

syndrome (ARDS) can occur in patients receiving Pegfilgrastim. Evaluate and lung infiltrates or respiratory distress after receiving Pegfilgrastim for stim in patients with ARDS.

including anaphylaxis can occur in patients receiving Pegfilgrastim. The occurred upon initial exposure. Allergic reactions, including anaphylaxis can discontinuation of initial anti-allergic treatment. Permanently discontinue

history of serious allergic reactions to Pegfilgrastim or Filgrastim.

Use in Patients With Sickle Cell Disorders

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

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte-colony stimulating factor (G-CSF) receptor through which Pegfilgrastim and Filgra has been found on tumor cell lines. The possibility that Pegfilgrastim acts as a growth factor for ar type, including myeloid malignancies and myelodysplasia, diseases for which Pegfilgrastim approved, cannot be excluded.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C

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

In animal reproduction studies, when pregnant rabbits received Pegfilgrastim at cumulative approximately 4 times the recommended human dose (based on body surface area), in embryolethality and spontaneous abortions occurred. Signs of maternal toxicity (reductions in bod gain/food consumption) and decreased fetal weights occurred at maternal doses approximately eq to the recommended human dose (based on body surface area). There were no structural ar observed in rabbit offspring at any dose tested. No evidence of reproductive/developmental occurred in the offspring of pregnant rats that received cumulative doses of Pegfilgrastim appro 10 times the recommended human dose (based on body surface area)

Nursing Mothers

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

USE IN CHILDREN

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

USE IN GERIATRIC PATIENTS

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

DRUG INTERACTION

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

OVERDOSE

The maximum amount of Pegfilgrastim that can be safely administered in single or multiple doses been determined. Single subcutaneous doses of 300 mcg/kg have been administered to 8 volunteers and 3 patients with non-small cell lung cancer without serious adverse effects. These experienced a mean maximum absolute neutrophil count (ANC) of 55 x 109/L, with a correspondi maximum WBC of 67 x 109/L. The absolute maximum ANC observed was 96 x 109/L corresponding absolute maximum WBC observed of 120 x 109/L. The duration of leukocytosis from 6 to 13 days. The effectiveness of leukapheresis in the management of symptomatic individu Pegfilgrastim-induced leukocytosis has not been studied.

STORAGE

Store the pre-filled syringe in original carton at 2° to 8° C, away from light. Do not freeze. Before i Pegfilgrast may be exposed to room temperature (not above 30° C) for a maximum of 72 hou product left at room temperature for more than 72 hours should be discarded. Pegfilgrast should vigorously shaken. Excessive shaken may aggregate Pegfilgrastim, rendering it biologically inactiv out of the reach of children.

PACKAGING

Pegfilgrast Injection: Each commercial box contains one auto guarded pre-filled syringe with one pad & one first aid bandage.

Manufactured By
BEACON®
Pharmaceuticals Limited
Bhaluka, Mymensingh, Bangladesh