Pegfilgrastim

INDICATIONS:

For chemotherapy-induced neutropenia prophylaxis, to decrease the incidence of febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia

For the treatment of acute radiation exposure, to increase survival, in patients who receive myelosuppressive doses of radiation

SAFETY ALERT:

1. **Adverse Drug Reactions**:

Severe

anaphylactoid reactions / Rapid / Incidence not known
acute respiratory distress syndrome (ARDS) / Early / Incidence not known
splenic rupture / Delayed / Incidence not known
sickle-cell crisis / Delayed / Incidence not known
vasculitis / Delayed / Incidence not known
azotemia / Delayed / Incidence not known
glomerulonephritis / Delayed / Incidence not known
capillary leak syndrome / Early / Incidence not known
aortitis / Delayed / Incidence not known

Moderate

bone pain / Delayed / 31.0-31.0
antibody formation / Delayed / 0-6.0
contact dermatitis / Delayed / Incidence not known
erythema / Early / Incidence not known
splenomegaly / Delayed / Incidence not known
bleeding / Early / Incidence not known
proteinuria / Delayed / Incidence not known
hematuria / Delayed / Incidence not known
hypotension / Rapid / Incidence not known
hypoalbuminemia / Delayed / Incidence not known
edema / Delayed / Incidence not known

Mild

leukocytosis / Delayed / 0-1.0
rash / Early / Incidence not known
pruritus / Rapid / Incidence not known

flushing / Rapid / Incidence not known
urticaria / Rapid / Incidence not known
injection site reaction / Rapid / Incidence not known
abdominal pain / Early / Incidence not known
malaise / Early / Incidence not known
back pain / Delayed / Incidence not known
fever / Early / Incidence not known

2. **Drug interactions**:
3. **Contraindications/Precautions:**

E. coli protein hypersensitivity

Pegfilgrastim is contraindicated for use in patients with a history of serious allergic reactions to pegfilgrastim or filgrastim products or any other component of the products. Therefore, use pegfilgrastim products with caution in patients with a history of E. coli protein hypersensitivity. Serious allergic reactions (e.g., anaphylaxis) have been reported. Most reactions occurred with the first dose and some reactions recurred days after treatment with anti-allergy medications. Permanently discontinue pegfilgrastim products in patients who experience a serious allergic reaction.

Sickle cell disease

Use pegfilgrastim products with caution in patients with sickle cell disease or sickle cell trait because severe sickle cell crises have been reported in this patient population; some cases were fatal. Monitor patients with sickle cell disease for symptoms of sickle cell crises such as pain or difficulty breathing. Discontinue pegfilgrastim if sickle cell crisis occurs.

Leukemia

Pegfilgrastim stimulates the production of hematopoietic stem cells and it may act as a growth factor for myeloid cells in myeloid malignancies (e.g., acute myelogenous leukemia, acute lymphocytic leukemia, myelodysplastic syndrome). Therefore, pegfilgrastim is not indicated for use in patients with myeloid malignancies. Additionally, increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone-imaging results.

Leukocytosis

Leukocytosis (WBC count greater than 100 x 109 cells/L) has been reported with pegfilgrastim use. Monitor complete blood counts during therapy with pegfilgrastim products.

Pregnancy

Retrospective studies in humans indicate that exposure to pegfilgrastim during pregnancy does not result in significant adverse effects on the fetus or neutropenia. However, preterm deliveries

have been reported in some patients.[63242] In pregnant rabbits, an increased rate of embryotic death and spontaneous abortion occurred following a pegfilgrastim cumulative dose of about 4-times the recommended human dose. Additionally, decreased fetal weight was observed at pegfilgrastim doses that were approximately equivalent to the recommended human dose. No developmental toxicity was observed in rat offspring following pegfilgrastim doses up to about 10-times the recommended human dose.

Breast-feeding

Weigh the potential risk to the infant against the potential benefits to the mother prior to initiating pegfilgrastim therapy in a woman who is breast-feeding. It is not known if pegfilgrastim is secreted in human milk or if it has effects on the breast-fed infant or milk production. Other filgrastim products are poorly secreted into breast milk and are not orally absorbed by neonates.