

## Important Safety Information - HCP

### Contraindication

- Stimufend (pegfilgrastim-fpgk) is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

### Splenic Rupture

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

### Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving pegfilgrastim products
- Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Stimufend
- Discontinue Stimufend in patients with ARDS

### Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products
- The majority of reported events occurred upon initial exposure and can recur within days after the discontinuation of initial anti-allergic treatment
- Permanently discontinue Stimufend in patients with serious allergic reactions

### Use in Patients with Sickle Cell Disorders

- In patients with sickle cell trait or disease, severe and sometimes fatal sickle cell crises can occur in patients receiving pegfilgrastim products
- Discontinue Stimufend if sickle cell crisis occurs

### Glomerulonephritis

- Has occurred in patients receiving pegfilgrastim products
- Diagnoses based on azotemia, hematuria, proteinuria, and renal biopsy
- Generally, events resolved after dose-reduction or discontinuation of pegfilgrastim products
- If suspected, evaluate for cause and if cause is likely, consider dose-reduction or interruption of Stimufend

### Leukocytosis

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- Increased white blood cell counts of  $100 \times 10^9/L$  have been observed
- Monitoring of complete blood count (CBC) during Stimufend therapy is recommended

### **Thrombocytopenia**

- Thrombocytopenia has been reported in patients receiving pegfilgrastim products. Monitor platelet counts

### **Capillary Leak Syndrome (CLS)**

- CLS has been reported after G-CSF administration, including pegfilgrastim products
- Characterized by hypotension, hypoalbuminemia, edema and hemoconcentration
- Episodes vary in frequency, severity and may be life-threatening if treatment is delayed
- Patients with symptoms should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care

### **Potential for Tumor Growth Stimulatory Effects on Malignant Cells**

- G-CSF receptor has been found on tumor cell lines
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.

### **Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer**

- MDS and AML have been associated with the use of pegfilgrastim products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

### **Aortitis**

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue Stimufend if aortitis is suspected

### **Nuclear Imaging**

- 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

### **Most common adverse reactions**

- Bone pain

- Pain in extremity

Please see **Stimufend full Prescribing Information**.

Stimufend Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.

### **Indication**

Stimufend is 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.

### **Limitations of Use**

Stimufend is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.