Stimufend®
pegfilgrastim-fpgk

DOSING AND ADMINISTRATION GUIDE

for STIMUFEND® (pegfilgrastim-fpgk), an FDA-approved biosimilar to Neulasta® (pegfilgrastim)

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.

IMPORTANT SAFETY INFORMATION

Contraindication

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

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Please see Important Safety Information throughout this brochure.
Please see accompanying full Prescribing Information for STIMUFEND.

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IMPORTANT SAFETY INFORMATION (cont'd)

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® (pegfilgrastim-fpgk)
- Discontinue STIMUFEND in patients with ARDS

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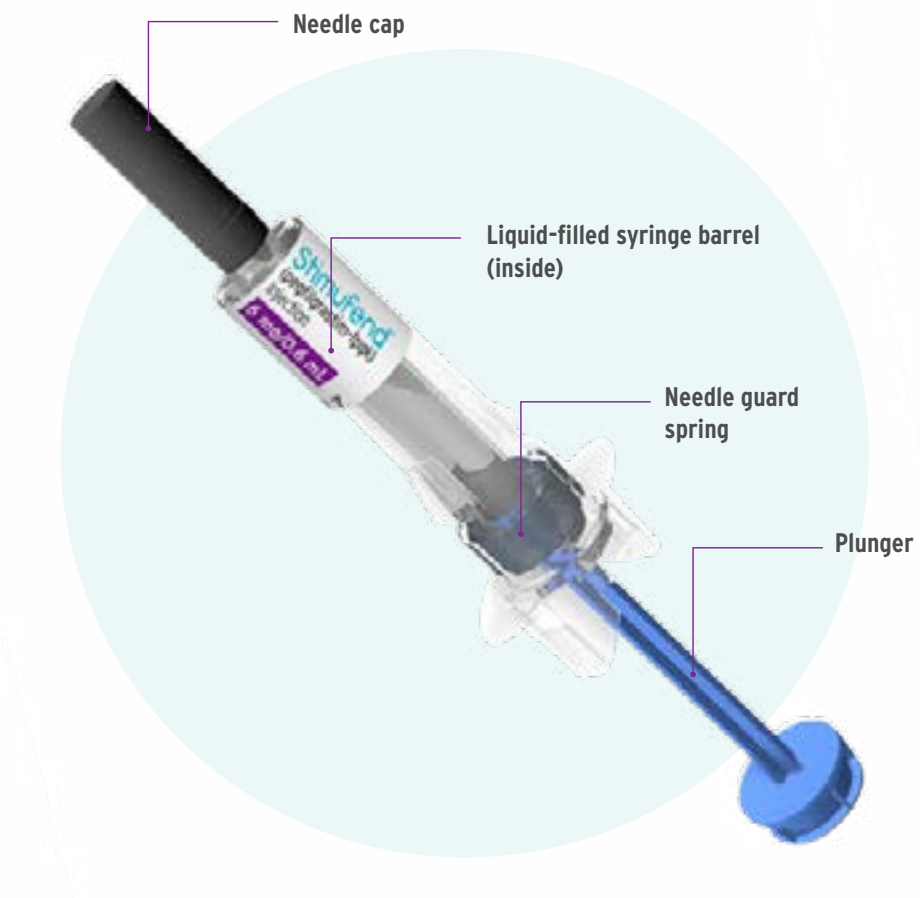
Product information

Stimufend® pegfilgrastim-fpgk

Features of the STIMUFEND® (pegfilgrastim-fpgk) pre-filled syringe

- STIMUFEND injection is a clear, colorless, preservative-free solution
- A pre-filled, single-dose syringe contains 6-mg pegfilgrastim-fpgk
  - Supplied in 0.6-mL pre-filled syringes for manual subcutaneous injection
- Provided in a dispensing pack containing 1 sterile 6-mg/0.6-mL pre-filled syringe
  - Includes a 27-gauge, half-inch needle with a Safe'n'Sound® passive needle guard
- The pre-filled syringe does not bear graduation marks and is designed to deliver the entire contents of the syringe (6 mg/0.6 mL)
- The needle cap on pre-filled syringes contains dry natural rubber (derived from latex); persons with latex allergies should not handle the needle cap of the syringe



IMPORTANT SAFETY INFORMATION (cont'd)

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

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Storage and handling

Stimufend® pegfilgrastim-fpgk

Keep STIMUFEND® (pegfilgrastim-fpgk) refrigerated between 36°F and 46°F (2°C and 8°C)

Do not freeze

Keep the pre-filled syringe in the original carton, to protect it from light

Discard the syringe if frozen or left in direct sunlight

Up to 72 hours

STIMUFEND can be stored at room temperature, 68°F to 77°F (20°C to 25°C), for up to 72 hours. Dispose of any STIMUFEND stored at room temperature for more than 72 hours

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

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STIMUFEND® dosing

Stimufend® pegfilgrastim-fpgk

Recommended dosing regimen

- The recommended dosage of STIMUFEND® (pegfilgrastim-fpgk) is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle
- **Do not** administer STIMUFEND between 14 days before and 24 hours after administration of cytotoxic chemotherapy
- The STIMUFEND pre-filled syringe is not designed to allow for direct administration of doses less than 6 mg/0.6 mL
- Direct administration to patients requiring dosing of less than 6 mg/0.6 mL is not recommended due to the potential for dosing errors
- **Do not** inject a dose of STIMUFEND to children weighing less than 45 kg from a STIMUFEND pre-filled syringe

Dosing of STIMUFEND for pediatric patients weighing less than 45 kg

Body Weight	STIMUFEND Dose	Volume to Administer
Less than 10 kg*	See below*	See below*
10–20 kg	1.5 mg	0.15 mL
21–30 kg	2.5 mg	0.25 mL
31–44 kg	4 mg	0.4 mL

*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of STIMUFEND.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Preparation and administration

Stimufend® pegfilgrastim-fpgk

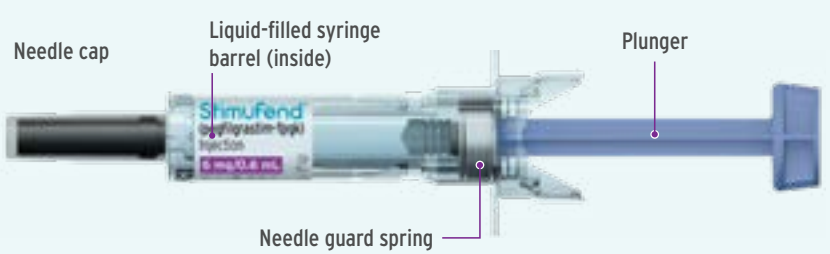
Considerations for using the pre-filled syringe

- ⊗ **Do not** shake the pre-filled syringe
- ⊗ **Do not** use STIMUFEND® (pegfilgrastim-fpgk) that has been frozen or left in direct sunlight
- ⊗ **Do not** use the pre-filled syringe if it has been dropped on a hard surface, as it may be broken even if there is no visible damage
- ⊗ **Do not** try to activate the clear needle guard before injecting

Please review the states of the pre-filled syringe before injection *(Figure A)* and after complete injection *(Figure B)*.

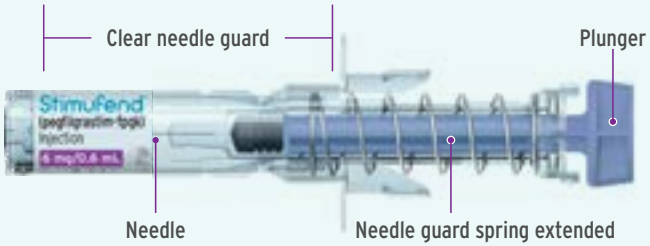
Before injection

Figure A



After complete injection
(clear needle guard locked in place)

Figure B



Note: Images for illustration purposes only.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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Preparation and administration (cont'd)

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Step 1: Prepare the pre-filled syringe

- Leave the syringe in its sealed plastic tray and let it come to room temperature on a clean, flat surface for 30 minutes before the injection
- **Do not** warm the syringe, such as in a microwave, hot water, or direct sunlight
- **Do not** remove the needle cap while allowing the syringe to reach room temperature

Step 2: Check the syringe

To remove the pre-filled syringe from the sealed plastic tray:

- Peel off the seal from the tray
- Place 2 fingers on either side, in the middle of the clear needle safety guard *(Figure C)*
- Pull the pre-filled syringe straight up and out of the tray
- **Do not** pick up the pre-filled syringe by the plunger or needle cap

Figure C

IMPORTANT SAFETY INFORMATION (cont'd)

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® (pegfilgrastim-fpgk) 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

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Preparation and administration (cont'd)

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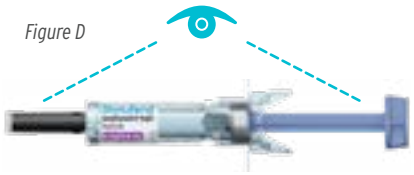
Step 2: Check the syringe (cont'd)

- Check that the pre-filled syringe, needle safety guard, and the needle cap are not cracked or damaged *(Figure D)*

Figure D

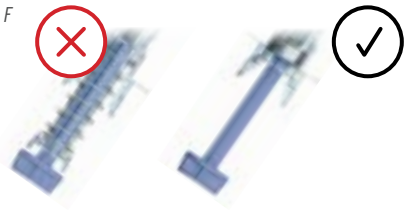


- Check that the needle cap is securely attached *(Figure E)*

Figure E

- Check that the needle safety guard spring is not extended *(Figure F)*

Figure F



- Check the liquid through the clear window to ensure the medicine is clear, colorless, and free of particles and flakes *(Figure G)*

Figure G

- ⊗ **Do not** use if the medicine is cloudy or colored, or if it has particles or flakes. Instead, throw away the syringe

IMPORTANT SAFETY INFORMATION (cont'd)

Most common adverse reactions

- Bone pain
- Pain in extremity

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Preparation and administration (cont'd)

Stimufend® pegfilgrastim-fpgk

Step 3: Prepare to inject

Choose an injection site *(Figures H and I)*

Injection sites include:

- Tops of the thighs
- Lower abdomen, at least 2 inches away from the navel
- Back of the arm
- Upper outer areas of the buttocks
- Only inject into the sites shown

Do not inject into an area that is sore, bruised, red, hard, or scarred, or where there are stretch marks or tattoos.

Do not inject through clothing.

Figure H

Figure I

Clean the injection site

- Wipe the skin of the injection site with an alcohol swab and let the skin dry *(Figure J)*
- **Do not** touch the injection site again before injecting

Figure J

IMPORTANT SAFETY INFORMATION (cont'd)

STIMUFEND® (pegfilgrastim-fpgk) Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only.

Preparation and administration (cont'd)

Stimufend® pegfilgrastim-fpgk

Step 4: Inject medicine

Pinch the skin

- Gently pinch the skin around the injection site without squeezing or touching the clean area *(Figure K)*

Figure K

Insert the needle

- Quickly insert the needle straight into the skin at a 45- to 90-degree angle *(Figure L)*

Figure L

Inject

- Use your thumb to gently push the plunger all the way down to inject the full dose *(Figure M)*
- The plunger must be pushed down fully to ensure the full dose has been injected *(Figure M)*

Figure M

Inject (cont'd)

- Hold the syringe firmly without moving it
- **Do not** remove the needle from the skin when the plunger reaches the end

Finish injection

- Slowly release your thumb upward, allowing the needle to move up into the clear needle guard, which should cover the entire needle *(Figure N)*
- **Do not** reuse a syringe in case of partial injection
- **Do not** try to recap the needle
- **Do not** rub the injection site
- Properly dispose of the used pre-filled syringe in a sharps container immediately after use

Figure N

IMPORTANT SAFETY INFORMATION (cont'd)

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi at 1-800-551-7176 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATION

STIMUFEND® (pegfilgrastim-fpgk) 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.

Limitations of Use

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

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KabiCare Patient Support Program by Fresenius Kabi

For additional information about STIMUFEND® (pegfilgrastim-fpgk), visit **STIMUFENDHCP.com**; also visit **KabiCare.us** to learn about our patient support programs and resources

Reference

STIMUFEND Prescribing Information. Fresenius Kabi USA, LLC; 2022.

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