



If your immune system is weakened due to chemotherapy for certain types of cancers

### STIMUFEND helps protect you against infection

### What is STIMUFEND® (pegfilgrastim-fpgk)?

STIMUFEND is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.

### **IMPORTANT SAFETY INFORMATION**

**Do not** take STIMUFEND if you have had a serious allergic reaction to pegfilgrastim or filgrastim.

Before you receive STIMUFEND, tell your healthcare provider about all of your healthcare conditions, including if you:

- Have a sickle cell disorder
- Are allergic to latex The needle cap on the prefilled syringe contains dry natural rubber (derived from latex).

## Why is my healthcare provider prescribing STIMUFEND® (pegfilgrastim-fpgk)?



## How does chemotherapy affect my immune system?

In the fight against cancer, chemotherapy targets cancer cells and healthy cells alike. While fighting cancer, chemotherapy can lower the number of white blood cells (neutrophils) in your body.

White blood cells are an important part of your body's immune response for fighting infections.

- A low white blood cell count (neutropenia) puts you at greater risk for infection
- Developing a fever when you have neutropenia (known as febrile neutropenia) can be life-threatening
- Neutropenia or febrile neutropenia can result in your healthcare provider needing to delay, reduce the dose of, or stop cancer treatment because you might have an infection







## Who may be at risk for infections due to neutropenia caused by chemotherapy?

If you are receiving chemotherapy as cancer treatment, select risk factors for neutropenia-related infections include:

- Being 65 years of age or older
- Prior exposure to chemotherapy or radiation
- Persistent low white blood cell count
- Tumor spreading to bone marrow
- Being underweight or having poor nutrition
- Difficulty doing basic physical activities, such as walking

- Recent surgery and/or open wounds
- Liver or kidney disease
- Other chronic diseases, such as diabetes and heart disease
- HIV infection
- Long-term weakened immune system after organ transplant

HIV, human immunodeficiency virus.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

- Have kidney problems
- Are pregnant or plan to become pregnant. It is not known if STIMUFEND may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if STIMUFEND passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### Warnings and Precautions

• **Spleen Rupture.** Your spleen may become enlarged and can rupture while taking STIMUFEND. A ruptured spleen can cause death. Call your healthcare provider right away if you have pain in the left upper stomach area or your left shoulder.

# STIMUFEND<sup>®</sup> (pegfilgrastim-fpgk) is a pegfilgrastim biosimilar

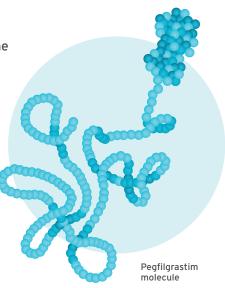


### What is STIMUFEND?

STIMUFEND is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection.

Pegfilgrastim is widely used and is given as an injection once every chemotherapy cycle to help prevent infection as indicated by febrile neutropenia.

STIMUFEND is a biosimilar to the original product, Neulasta® (pegfilgrastim).



### **IMPORTANT SAFETY INFORMATION (cont'd)**

- A serious lung problem called Acute Respiratory Distress Syndrome (ARDS). Call your healthcare provider or get emergency medical help right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- Serious Allergic Reactions. STIMUFEND can cause serious allergic reactions. These reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness, swelling around your mouth or eyes, fast heart rate and sweating. Call your healthcare provider or get emergency medical help right away if you have any of these symptoms.
- Sickle Cell Crises. You may have a serious sickle cell crisis, which could lead to death, if you have a sickle cell disorder and receive STIMUFEND. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.





### What is a biosimilar?

A biosimilar is a medicine that is highly similar to the original product with no clinically meaningful differences in safety, purity, or effectiveness.

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How does a biosimilar compare to the original product?

• Also made from living cells

- Just as effective
- Works in the same way in your body
  - Has the same level of purity



Why are biosimilars important?

- Help reduce costs for patients and healthcare systems
- Encourage innovation in health care
- Increased availability to more patients in need



"FDA requires biosimilar and interchangeable biological products meet the Agency's rigorous approval standards. That means patients and health care professionals will be able to rely upon the safety and effectiveness of the biosimilar or interchangeable product, just as they would the reference [original] product."

– US Food and Drug Administration

### The role of STIMUFEND® (pegfilgrastim-fpgk) during chemotherapy



### How can STIMUFEND help me?

STIMUFEND stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection. STIMUFEND is administered at least 24 hours after you receive chemotherapy. STIMUFEND is not a chemotherapy drug.



### It is important that you receive STIMUFEND after each cycle of chemotherapy.

- Missing a dose of STIMUFEND significantly increases your risk of infection
- An infection can result in your healthcare provider needing to delay, reduce the dose of, or stop cancer treatment

As a result, it is important to be consistent in receiving STIMUFEND. Talk to your healthcare provider if you have any questions or visit <u>STIMUFEND.COM</u> for additional information.



### How do I receive STIMUFEND?

You will receive STIMUFEND at least 24 hours after your chemotherapy treatment.

STIMUFEND needs to be injected only once during each chemotherapy cycle.

STIMUFEND is administered as an injection under the skin (subcutaneous injection) by your healthcare provider.

Ask your healthcare provider about being able to administer STIMUFEND at home, by yourself, or with the help of your caregiver.



At home, store STIMUFEND in its original carton in the refrigerator between 36°F to 46°F (2°C to 8°C).

Take STIMUFEND out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.



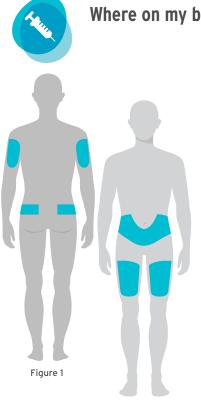


Figure 2

### Where on my body is STIMUFEND administered?

Your healthcare provider, you, or your caregiver may administer STIMUFEND at the following injection sites:

By healthcare provider or caregiver only (Figure 1):

- Backs of the arms
- Upper outer areas of the buttocks

By healthcare provider, caregiver, or you (Figure 2):

- Tops of the thighs
- Stomach area (2 inches away from the belly button)



Do not try to inject STIMUFEND unless you or your caregiver has received training from your healthcare provider.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

- **Kidney injury (glomerulonephritis).** STIMUFEND can cause kidney injury. Call your healthcare provider right away if you develop any of the following symptoms: swelling of your face or ankles, blood in your urine or dark colored urine, or you urinate less than usual.
- Increased white blood cell count (leukocytosis). Your healthcare provider will check your blood during treatment with STIMUFEND.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with STIMUFEND. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with STIMUFEND. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.

### Important information about STIMUFEND® (pegfilgrastim-fpgk)



### What can I expect with STIMUFEND?

The most common side effect associated with STIMUFEND is pain in the bones, arms, and legs. These are not all the possible side effects with STIMUFEND. Talk to your healthcare provider about managing bone pain and any other side effects.

Be sure to review the Patient Information for additional information on other side effects.

Important things to remember during treatment

- Apply a warm compress if you experience pain, redness, or swelling at the injection site, and contact your healthcare provider
- Ask your healthcare provider whether you can take a mild pain medicine, such as acetaminophen, for bone pain
- Bone pain that persists despite taking a recommended pain reliever requires medical attention. Notify your healthcare provider immediately if bone pain lasts for 24 hours
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Tell your healthcare provider about symptoms or side effects, so they can help you manage the problem



### When should I call my healthcare provider?

If you have a fever of 100.4°F or higher, call your healthcare provider or 911 immediately. Having a fever could be a sign of febrile neutropenia (fever with low white blood cell count). In addition, let your healthcare provider know about any new skin rashes or if you have bleeding that does not stop.

Look out for other signs of infections

• Pus or yellowish discharge

Sore throat

Shortness of breath

Chills

- Rapid heartbeat
- Burning or pain when urinating
- Sores or white patches in the mo**uth**

While this information is intended as a guide, always follow the instructions provided by your healthcare provider.

Abdominal (belly) pain





### What role can I play in reducing the risk of infections?

If you are receiving chemotherapy as cancer treatment, it is very important to take care of yourself in order to help reduce the risk of infection. The following tips may help you prevent an infection from occurring.

Lifestyle tips

- Washing your hands often is the single most important thing you can do (if you do not have soap handy, carry hand sanitizer)
- ✓ Avoid large crowds because they may include people who are ill
- Consider wearing a face mask in public
- Use lotion to help prevent dry skin and cracking
- Be careful about cuts and scrapes that can lead to infection
- Cover any cuts and scrapes with clean bandages until they heal
- Cook food thoroughly to kill infection-causing bacteria that may be in raw food

### **IMPORTANT SAFETY INFORMATION (cont'd)**

- Capillary Leak Syndrome. STIMUFEND can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - -Swelling or puffiness and are urinating less than usual
  - -Trouble breathing
  - -Swelling of your stomach area (abdomen) and feeling of fullness
  - -Dizziness or feeling faint
  - -A general feeling of tiredness

# Patient support resources for STIMUFEND® (pegfilgrastim-fpgk)

Fresenius Kabi is committed to providing you comprehensive support throughout your treatment journey.

### Access to treatment

- Assistance with navigating insurance to obtain coverage and with reviewing patient benefits
- Financial assistance programs available, including copay assistance with out-ofpocket costs as little as \$0 for patients with commercial or private insurance\*

### Educational and support resources

- Nurse educators dedicated to disease, treatment, and medication education<sup>†</sup>
- Educational materials covering lifestyle modifications, nutrition, and health and well-being

### **Coordinated logistical support**

- A Bridge to Therapy program\* that ensures you can receive STIMUFEND without delay while you are waiting for insurance approval
- Identification of potential treatment-related transportation and lodging benefits that may be provided by your insurance or through independent foundations<sup>‡</sup>
- \*Eligibility criteria apply. Patients are not eligible for commercial copay assistance and Bridge to Therapy support if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program.
- <sup>†</sup>Nurse support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

<sup>‡</sup>Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

- Myelodysplastic syndrome and acute myeloid leukemia. If you have breast cancer or lung cancer, when STIMUFEND is used with chemotherapy and radiation therapy, or with radiation therapy alone, you may have an increased risk of developing a precancerous blood condition called myelodysplastic syndrome (MDS) or a blood cancer called acute myeloid leukemia (AML). Symptoms of MDS and AML may include tiredness, fever, and easy bruising or bleeding. Call your healthcare provider if you develop these symptoms during treatment with STIMUFEND.
- Inflammation of the aorta (aortitis). Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) has been reported in patients who received STIMUFEND. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.



#### Copay assistance\* and financial support

KabiCare™ provides additional support programs to eligible patients.\*

What type of insurance do you have?

Commercial or private insurance	If you have commercial or private insurance, you may be eligible* for the copay assistance program that lowers your out-of-pocket costs to as little as \$0/month for STIMUFEND, with an annual maximum.
Government insurance (Medicare/Medicaid)	If you have government insurance, but your plan does not cover STIMUFEND, you may be eligible for assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs that may be able to help you afford STIMUFEND copay costs. <sup>†</sup>
Uninsured/ Underinsured <sup>‡</sup>	If you do not have insurance and/or cannot afford STIMUFEND, you may be eligible for additional assistance through the Patient Assistance Program (PAP) or through independent nonprofit patient assistance programs. <sup>†</sup>

Pay as little as \$0 copay for each dose of STIMUFEND\*



Ask your healthcare provider to help you enroll, if you qualify for copay assistance.

If you receive prescription reimbursement through your local, state, or federal government, visit <u>KabiCare.us</u> or call 1.833.KABICARE (1.833.522.4227).

\*Eligibility criteria apply. Patients are not eligible for commercial copay assistance if the prescription is eligible to be reimbursed, in whole or in part, by any state or federal healthcare program. \*Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs. \*Underinsured means that your health insurance plan does not cover STIMUFEND.





### Where can I find more resources or information?

For additional support along your treatment journey, the following websites may provide helpful information:



### For financial support

- PAN Foundation: panfoundation.org
- HealthWell Foundation: healthwellfoundation.org



#### For general cancer information

- American Cancer Society: cancer.org
- Cancer.Net
- Mayo Clinic: mayoclinic.org
- MD Anderson Cancer Center: mdanderson.org
- CancerConnect: <u>cancerconnect.com</u>



#### For cancer communities

- Cancer Hope Network: cancerhopenetwork.org
- Cancer Support Community: cancersupportcommunity.org
- 4th Angel Mentoring Program: 4thangel.ccf.org
- Inspire: inspire.com
- MyLifeLine: mylifeline.org
- CancerCare: cancercare.org

We are committed to being your partner in providing the support you need for your journey with STIMUFEND® (pegfilgrastim-fpgk).



To learn more about STIMUFEND, visit <u>STIMUFEND.COM</u>



### **IMPORTANT SAFETY INFORMATION (cont'd)**

The most common side effect of STIMUFEND is pain in your bones and in your arms and legs.

These are not all the possible side effects of STIMUFEND. Call your healthcare provider for medical advice about side effects. You may report negative side effects to the FDA at **1-800-FDA-1088**.

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

Please see full Prescribing Information, Patient Information, and Instructions for Use.

