GRANIX® for subcutaneous use

The content of this guide is intended to instruct on the use of the safety guard needle device when administering GRANIX.

GRANIX should be administered by a healthcare practitioner.

GRANIX is a leukocyte growth factor indicated for reduction in the duration of severe neutropenia in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Important Safety Information

» Splenic rupture: Splenic rupture, including fatal cases, can occur following the administration of human granulocyte colony-stimulating factors (hG-CSFs). Discontinue GRANIX® (tbo-filgrastim) Injection and evaluate for an enlarged spleen or splenic rupture in patients who report upper abdominal or shoulder pain after receiving GRANIX.

» Acute respiratory distress syndrome (ARDS): ARDS can occur in patients receiving hG-CSFs. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

» Allergic reactions: Serious allergic reactions, including anaphylaxis, can occur in patients receiving hG-CSFs. Reactions can occur on initial exposure. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.

» Use in patients with sickle cell disease: Severe and sometimes fatal sickle cell crisis can occur in patients with sickle cell disease receiving hG-CSFs. Consider the potential risks and benefits prior to the administration of GRANIX in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

» Capillary leak syndrome (CLS): CLS can occur in patients receiving hG-CSFs and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of CLS 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: The granulocyte colony-stimulating factor (G-CSF) receptor, through which GRANIX acts, has been found on tumor cell lines. The possibility that GRANIX acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which GRANIX is not approved, cannot be excluded.

» Most common treatment-emergent adverse reaction: The most common treatment-emergent adverse reaction that occurred in patients treated with GRANIX at the recommended dose with an incidence of at least 1% or greater and two times more frequent than in the placebo group was bone pain. For more information on GRANIX, please see accompanying Full Prescribing Information.

References:
1. GRANIX® (tbo-filgrastim) Injection Prescribing Information. North Wales, PA: Teva Pharmaceuticals; 2014.
2. BD Hypak™ SCFTM (Sterile) and Bulk (Non-Sterile) Syringe Systems Biologics Master File BB-MF-10052; 1.

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For more information on GRANIX, visit www.GRANIXhcp.com
Dosage & Administration

GRANIX® (tbo-filgrastim) Injection
Once-Daily Dosing

Recommended Dose: 5 mcg/kg per day

Administered by a healthcare professional as a subcutaneous injection

In clinical studies, GRANIX was administered at 5 mcg/kg subcutaneous once daily beginning 1 day after chemotherapy for at least 5 days and continued for a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.

**Dose 1**

The first dose should be administered no earlier than 24 hours following myelosuppressive chemotherapy, do not administer within the 24 hours prior to chemotherapy.

**Subsequent Daily Doses**

Continue until the expected neutrophil nadir is passed and the neutrophil count has recovered to the normal range. Monitor complete blood count (CBC) prior to chemotherapy and twice per week until recovery.

In clinical studies, GRANIX was administered at 5 mcg/kg subcutaneous once daily beginning 1 day after chemotherapy for at least 5 days and continued for a maximum of 14 days or until an ANC of ≥10,000 x 10^6/L after nadir was reached.

**Step 1**

Hold the syringe assembly by the open sides of the device and remove the needle shield.

*Solution shown as a blue fluid in this illustration for demonstration purposes only.

**Step 2**

Expel any extra volume depending on dose needed.

**Step 3**

Inject GRANIX subcutaneously as recommended.

Push the plunger as far as it will go to inject all the medication. Injection of the entire prefilled syringe contents is necessary to activate the needle guard.

**Step 4**

With the plunger still pressed all the way down, remove the needle from the skin.

Be sure the plunger is still pressed all the way down.

**Step 5**

Slowly let go of the plunger and allow the empty syringe to move up inside the device until the entire needle is guarded.

**Step 6**

Discard the syringe assembly in approved containers.

Single-use syringe – discard unused portion. Any unused product or waste material should be disposed of in accordance with local requirements.

---

Please see Important Safety Information on reverse and accompanying Full Prescribing Information.
GRANIX® (tbo-filgrastim) is a leukocyte growth factor indicated for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. (1)

2.1 Dosage

The recommended dose of GRANIX is 5 mcg/kg per day administered as a subcutaneous injection. Administer the first dose no earlier than 24 hours following myelosuppressive chemotherapy. Do not administer within 24 hours prior to chemotherapy (2.1)

DOSAGE FORMS AND STRENGTHS

Injection: 300 mcg/0.5 mL solution in single-use prefilled syringe
Injection: 480 mcg/0.8 mL solution in single-use prefilled syringe

CONTRAINDICATIONS

None.

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Dosage

2.2 General Considerations for Administration

2.3 Instructions for Use of the Safety Needle Guard Device by Healthcare Professionals

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

5.2 Acute Respiratory Distress Syndrome (ARDS)

5.3 Allergic Reactions

5.4 Use in Patients with Sickle Cell Disease

5.5 Capillary Leak Syndrome

5.6 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

6.2 Immunogenicity

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Nursing Mothers

8.3 Pediatric Use

8.4 Geriatric Use

8.5 Renal Impairment

8.6 Hepatic Impairment

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

PATIENT INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

2.3 Instructions for Use of the Safety Needle Guard Device by Healthcare Professionals

Hold the syringe assembly by the open sides of the device and remove the needle shield.

Expel any extra volume depending on dose needed.

Inject GRANIX subcutaneously as recommended [see General Considerations for Administration (2.2)].

Push the plunger as far as it will go to inject all the medication. Injection of the entire prefilled syringe contents is necessary to activate the needle guard.
GRANIX® (tbo-filgrastim) injection

With the plunger still pressed all the way down, remove the needle from the skin.

Slowly let go of the plunger and allow the empty syringe to move up inside the device until the entire needle is guarded.

Discard the syringe assembly in approved containers.

3 DOSAGE FORMS AND STRENGTHS

Injection: 300 mcg/0.5 mL solution in single-use prefilled syringe
Injection: 480 mcg/0.8 mL solution in single-use prefilled syringe

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Splenic Rupture

Splenic rupture, including fatal cases, can occur following administration of human granulocyte colony-stimulating factors. In patients who report upper abdominal or shoulder pain after receiving GRANIX, discontinue GRANIX and evaluate for an enlarged spleen or splenic rupture.

5.2 Acute Respiratory Distress Syndrome (ARDS)

Acute respiratory distress syndrome (ARDS) can occur in patients receiving human granulocyte colony-stimulating factors. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving GRANIX, for ARDS. Discontinue GRANIX in patients with ARDS.

5.3 Allergic Reactions

Serious allergic reactions including anaphylaxis can occur in patients receiving human granulocyte colony-stimulating factors. Reactions can occur on initial exposure. The administration of antihistamines, steroids, bronchodilators, and/or epinephrine may reduce the severity of the reactions. Permanently discontinue GRANIX in patients with serious allergic reactions. Do not administer GRANIX to patients with a history of serious allergic reactions to filgrastim or pegfilgrastim.

5.4 Use in Patients with Sickle Cell Disease

Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disease receiving human granulocyte colony-stimulating factors. Consider the potential risks and benefits prior to the administration of human granulocyte colony-stimulating factors in patients with sickle cell disease. Discontinue GRANIX in patients undergoing a sickle cell crisis.

5.5 Capillary Leak Syndrome

Capillary leak syndrome (CLS) can occur in patients receiving human granulocyte colony-stimulating factors and is characterized by hypotension, hypoalbuminemia, edema and hemococoncentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

5.6 Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The following potential serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Splenic Rupture  [see Warnings and Precautions (5.1)]
- Acute Respiratory Distress Syndrome  [see Warnings and Precautions (5.2)]
- Serious Allergic Reactions  [see Warnings and Precautions (5.3)]
- Use in Patients with Sickle Cell Disease  [see Warnings and Precautions (5.4)]
- Capillary Leak Syndrome  [see Warnings and Precautions (5.5)]
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells  [see Warnings and Precautions (5.6)]
10 OVERDOSAGE
No case of overdose has been reported.

11 DESCRIPTION
Tbo-filgrastim is a non-glycosylated recombinant methionyl human granulocyte colony-stimulating growth factor (r-metHuG-CSF) manufactured by recombinant DNA technology using the bacterium strain E coli K802. It has a molecular weight of approximately 18.8 kDa and is composed of 175 amino acids. The endogenous human G-CSF is glycosylated and does not have the additional methionine amino acid residue in its NH₂-terminal end. The product is a sterile, clear, colorless, preservative-free solution containing tbo-filgrastim, glacial acetic acid, sorbitol, polysorbate 80, sodium hydrosxide, and Water for Injection. The product is available in single-use prefilled syringes that contain either 300 mcg or 480 mcg of tbo-filgrastim at a fill volume of 0.5 mL or 0.8 mL, respectively. See table below for product composition of each single-use prefilled syringe.

<table>
<thead>
<tr>
<th>Product Composition</th>
<th>Tbo-filgrastim</th>
<th>Glacial Acetic Acid</th>
<th>Polysorbate 80</th>
<th>Sorbitol</th>
<th>Sodium Hydrosxide</th>
<th>Water for Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mcg/0.5 mL Syringe</td>
<td>300 mcg</td>
<td>0.3 mg</td>
<td>0.0275 mg</td>
<td>25 mg</td>
<td>q.s. to pH 4.2</td>
<td>q.s. to 0.5 mL</td>
</tr>
<tr>
<td>480 mcg/0.8 mL Syringe</td>
<td>480 mcg</td>
<td>0.48 mg</td>
<td>0.044 mg</td>
<td>40 mg</td>
<td>q.s. to pH 4.2</td>
<td>q.s. to 0.8 mL</td>
</tr>
</tbody>
</table>

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Tbo-filgrastim is a human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. Tbo-filgrastim binds to G-CSF receptors and stimulates proliferation of neutrophils. G-CSF is known to stimulate differentiation commitment and some end-cell functional activation, which increases neutrophil counts and activity.

12.2 Pharmacodynamics
In the clinical trials of patients with cancer, the time to the ANCmax was between 3 to 5 days and returned to baseline by 21 days following completion of chemotherapy. In the healthy volunteer trials, doubling the tbo-filgrastim subcutaneous dose from 5 to 10 mcg/kg resulted in a 16%-19% increase in the ANCmax and a 33%-36% increase in the area under the effect curve for ANC.

12.3 Pharmacokinetics
In healthy subjects, the absolute bioavailability of 5 mcg/kg subcutaneous tbo-filgrastim was 33%. Increasing the dose of tbo-filgrastim from 5 to 10 mcg/kg in these healthy subjects resulted in an approximately 200% increase in both the maximum concentration (Cmax) and the area under the curve (AUC0-24h) of the drug.

Cardiac Electrophysiology
At the maximum recommended intravenous dose of 5 μg/kg, tbo-filgrastim did not result in an approximately 200% increase in both the maximum concentration (Cmax) and the area under the curve (AUC0-24h) of the drug.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity and genetic toxicity studies have not been conducted with tbo-filgrastim. A fertility study was not conducted with tbo-filgrastim. Toxicology studies of up to 26 weeks in rats or monkeys did not reveal findings in male or female reproductive organs that would suggest impairment of fertility.

14 CLINICAL STUDIES
The efficacy of GRANIX® in a multinational, multicenter, randomized and controlled Phase 3 study in 348 chemotherapy-naive patients with high-risk stage II, stage III, or stage IV breast cancer receiving doxorubicin (80 mg/m²) and docetaxel (75 mg/m²) during a 21-day cycle has been evaluated. The median age of the patients was 50 years (range 25 to 75 years) with 99% female and 86% Caucasian.

GRANIX, placebo, and the non-US-approved filgrastim product were administered at 5 mcg/kg subcutaneously once daily beginning one day after chemotherapy for at least five days and continued to a maximum of 14 days or until an ANC of ≥10,000 x 10³/L after nadir was reached. GRANIX was superior to placebo in duration of severe neutropenia (DSN) with a statistically significant reduction in DSN (1.1 days vs. 3.8 days, p < 0.0001).

16 HOW SUPPLIED/STORAGE AND HANDLING
GRANIX solution for injection is supplied as a single-use, preservative-free, prefilled syringe of Type I glass which has a permanently attached stainless steel needle. Syringes may be supplied with or without an UltraSafe Passive® Needle Guard. The active substance is tbo-filgrastim.

GRANIX 300 mcg/0.5 mL: Each prefilled syringe contains 300 mcg of tbo-filgrastim in 0.5 mL solution with a clear plunger.

GRANIX 480 mcg/0.8 mL: Each prefilled syringe contains 480 mcg of tbo-filgrastim in 0.8 mL solution.

Packaging:
- Pack of 1 without a safety needle guard (for patients and caregivers): NDC 63459-910-17
- Pack of 5 without a safety needle guard (for patients and caregivers): NDC 63459-910-36

The product is a sterile, clear, colorless, preservative-free solution containing tbo-filgrastim, glacial acetic acid, sorbitol, polysorbate 80, sodium hydrosxide, and Water for Injection. The product is available in single-use prefilled syringes that contain either 300 mcg or 480 mcg of tbo-filgrastim at a fill volume of 0.5 mL or 0.8 mL, respectively. See table below for product composition of each single-use prefilled syringe.

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GRANIX® (tbo-filgrastim) injection

GRANIX® (tbo-filgrastim) injection

GRANIX® (tbo-filgrastim) injection

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GRANIX® (tbo-filgrastim) injection

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GRANIX® (tbo-filgrastim) injection

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What is GRANIX?
GRANIX is a prescription medicine:
• used in people with certain types of cancer (non-myeloid malignancies), who are receiving chemotherapy that affects the bone marrow
• given to help decrease the length of time that the number of certain white blood cells (neutrophils) are very low (severe neutropenia). Neutrophils are white blood cells that are important in fighting bacterial infections.

It is not known if GRANIX is safe and effective in children under 18 years of age.

What should I tell my doctor before I receive GRANIX?
Before you receive GRANIX, tell your doctor if you:
• have sickle cell anemia or other blood problem
• plan to have bone scans or tests
• are allergic to filgrastim (Neupogen) or pegfilgrastim (Neulasta)
• have any other medical conditions
• are pregnant or plan to become pregnant. It is not known if GRANIX will harm your unborn baby.
• are breastfeeding or plan to breastfeed. It is not known if GRANIX passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive GRANIX?
• GRANIX is given by an injection under your skin (subcutaneous).
• Your first dose of GRANIX is given at least 24 hours after you receive your chemotherapy.
• GRANIX injections are usually given 1 time each day until your white blood cell count returns to normal.
• Your doctor will test your blood before your chemotherapy and during your GRANIX treatment until your white blood cell count returns to normal.
• Keep all of your appointments for your GRANIX injections and blood tests.

How should I use GRANIX?
• GRANIX injections can be given by a doctor or nurse, or your doctor may decide that your injections can be given at home by you or your caregiver. If GRANIX is taken at home, follow the detailed Instructions for Use included with your GRANIX package for information about the right way to:
  • Store GRANIX
  • Read the syringe markings and adjust the amount of medicine
  • Prepare and administer an injection.
• Your doctor will tell you how much GRANIX to inject and the timing of when to inject it. Inject GRANIX exactly as instructed.
• Do not change your dose unless your doctor tells you to.
• You or your caregiver will be shown how to prepare for an injection and how to inject GRANIX before you use it for the first time.
• Take your first dose of GRANIX at least 24 hours after you receive your chemotherapy.
• If you miss a dose or forget to take your dose of GRANIX, speak to your doctor about when to take your next dose.
• If you use too much GRANIX, call your doctor right away.
• If you or your caregiver get GRANIX on your skin, wash the area with soap and water.

What is the possible side effects of GRANIX?
GRANIX can cause serious side effects, including:
• Spleen rupture, which can cause death. Call your doctor right away if you have pain in your left upper stomach area or left shoulder area while taking GRANIX. This pain could mean your spleen is enlarged or ruptured.
• A serious lung problem called Acute Respiratory Distress Syndrome (ARDS). Get medical help right away if you have any of these symptoms of Acute Respiratory Distress Syndrome (ARDS):
  • fever
  • shortness of breath
  • trouble breathing
• Serious allergic reactions. If you have a serious allergic reaction during a GRANIX injection, stop giving yourself the injections and call your doctor right away. Symptoms of serious allergic reaction can occur during or after your injection and include:
  • a rash over the whole body
  • shortness of breath
  • trouble breathing (wheezing)
  • dizziness
  • swelling around the mouth or eyes
  • fast heart rate
  • sweating
• Severe sickle cell crisis in people with a sickle cell disease. If you have sickle cell disease, talk to your doctor about the risks of taking GRANIX.

The most common side effect of GRANIX is bone pain. Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of GRANIX. For a complete list, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about GRANIX
Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. This Patient Information leaflet summarizes the most important information about GRANIX. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about GRANIX that is written for health professionals.

For more information, call 1-800-896-5855.

What are the ingredients in GRANIX?
Active ingredient: tbo-filgrastim
Inactive ingredient: glacial acetic acid, sorbitol, polysorbate 80, sodium hydrosxide, and Water for Injection.

This Patient Information has been approved by the U.S. Food and Drug Administration.

TBOPL-004

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GRANIX® (tbo-filgrastim) injection

Instructions for Use
GRANIX (GRAN-icks)
(tbo-filgrastim)
Injection, for subcutaneous use

Important: Keep the GRANIX syringe out of the reach of children.

About the GRANIX syringe
Depending on the prescription that your doctor gave you, you will receive a syringe that provides a dose of either 0.1mL to 0.5mL or 0.1mL to 0.8mL. If you are prescribed a dose over 0.8mL, two syringes will be required to reach your prescribed dose. Your doctor will determine how many syringes and the correct dose in milliliters (mL) you will need to give based on your body weight. You should continue to give GRANIX daily until your doctor informs you that your white blood cell count has returned to normal.

Make sure you understand the following:
• How to store your syringes.
• How to read the syringe markings.
• How to adjust the amount of GRANIX in the syringe for your prescribed dose.
• How to prepare and give the injection.

Do not shake syringes.
Do not remove the needle cap until you are ready to inject.
Do not re-use a syringe. The syringe is for single-use only.
Do not use earlier than 24 hours following the end of your chemotherapy cycle.

Dosing schedule
Inject your total daily dose 1 time each day as prescribed by your doctor, starting at least 24 hours (1 day) after the end of your chemotherapy cycle. You should continue to give GRANIX daily until your white blood cell count returns to normal.

Determining how many syringes you need for your daily dose
• If your prescribed daily dose is 0.5mL or less, use 1 syringe.
• If your prescribed daily dose is 0.8mL or less, use 1 syringe.
• If your prescribed daily dose is more than 0.8mL you will need to prepare 2 syringes in order to match your prescribed dose:
  ○ Adjust your first syringe to 0.8mL.
  ○ Adjust your second syringe to the additional amount required to make up your total prescribed dose.
  ○ Make sure the amounts in both syringes add up to your prescribed dose. (See the table to the right to determine how much medicine should be in each syringe).

For example: If your prescribed dose is 1mL you would prepare 1 syringe with 0.8mL and a second syringe with 0.2mL.

How to read the syringe markings
What the markings on the syringe mean:
The syringe is labeled in 0.1mL unit increments from 0.1mL to 0.8mL.

How to adjust the medicine level for your prescribed dose
• When setting your dose, (See 2C) you will line up the top edge of the grey rubber stopper with the line on the syringe scale that matches your prescribed dose.

How to store your GRANIX syringes
• Always store the GRANIX syringes in a refrigerator at a temperature between 36°F to 46°F (2°C to 8°C).
• Always store the syringes in the carton to protect them from light.
• GRANIX syringes can be left unrefrigerated for a single period of up to 5 days, and if not used can be returned to the refrigerator.
• When preparing to inject, you will need to let the syringe(s) adjust to room temperature for 30 minutes.
• Throw away (dispose of) your syringes if stored at room temperature for more than 5 days.
Granix® injection

• “Granix® injection” is not listed on the carton.

1. Prepare for injection
1A Each time you inject a dose gather the following supplies:
• Granix® syringe(s)
• Alcohol swabs
• Paper towel
• Cotton ball or gauze
• Bandage (optional)
• Sharps container (hard-walled container for discarding syringes)

1B Take the carton with the syringe(s) out of the refrigerator

1C Check the label and the expiration date on the side of the carton

Important: Do not inject if:
• “Granix® (tbo-filgrastim)” is not listed on the carton.
• The expiration date on the syringe label has passed.

1D Remove the syringe(s) from the carton
Open the carton by breaking the tamper proof seal and lifting the lid. Remove the number of syringes required for your daily dose by grasping each at the middle of the syringe body.
After removing your required number of syringes, place the carton back in the refrigerator.

1E Look carefully at the syringe(s) and the medicine
Hold the syringe body and check to make sure it is not damaged.
Inspect the medicine in the syringe. Granix should be a clear liquid.

Important: Do not inject if:
• Granix® (tbo-filgrastim) is not listed on the syringe label.
• The medicine is cloudy, discolored, or foamy.
• The medicine contains lumps, flakes, or particles.

1F Wait 30 minutes for the syringe(s) to warm to room temperature
Wait 30 minutes for Granix to naturally warm to room temperature. This will provide a more comfortable injection.

1G Wash your hands
When ready to inject, wash your hands with soap and warm water and dry thoroughly with a clean towel.

1H Choose an injection site
The recommended injection sites are:
If you are self-injecting:
Stomach area (abdomen): Except for a 2-inch area around the navel (belly button).
Thighs: Top or middle area of thighs.
If a caregiver is injecting Granix for you:
Arms: Fleshy areas on upper, back part of the arm.
Upper hip or buttock: Fleshy areas around the back of the upper hips and upper sides of the buttocks.
If 2 injections will be performed, then the second injection should be at least 1 inch away from the first injection.

Do not use the top of the cone or the middle or lower edges of the grey stopper to measure your dose.

Injection procedure (follow the steps below for each day of dosing)

1. Prepare for injection

Example:

GRANIX® syringe

Wait 30 Minutes

CONTINUE TO SIDE 2 FOR INJECTION PROCEDURE
Do not inject into areas that are tender, red, bruised, hard, or have scars or stretch marks.

Important:

- You should select a different injection site each time you give yourself an injection.
- If you want to use the same injection site for a dose requiring 2 injections, make sure the second injection site is at least 1 inch away from the first injection site.

1A Clean the injection site using an alcohol swab

Allow site to dry for 5-10 seconds to avoid stinging.
If giving 2 injections, then the distance between the 2 injection sites should be at least 1 inch apart.

Do not touch or blow on site after cleaning.

2. Adjust medicine level for your prescribed dose

2A Remove the needle cap from the syringe

Place a paper towel on the table.
To remove the needle cap, hold the body of the syringe firmly with 1 hand (with the needle facing away from you).
Pull the needle cap straight off, extending your hand away from the needle.

Note: Throw away the needle cap in a sharps container.
Do not recap the needle now or after the injection.

2B Hold the syringe upright and tap

Hold the syringe upright (needle pointing up), as shown. Gently tap the barrel with your fingers to make sure any air bubbles rise to the top.

2C Slowly and carefully adjust the medicine level

Hold the syringe with the needle pointing up and slightly away from you, as shown. Make sure you can easily see the syringe markings and numbers.

Holding the plunger as shown, very slowly and carefully push the plunger up until the top edge of the grey rubber stopper is even with the line that corresponds to your prescribed dose.

Note: It is OK for the medicine to make contact with your skin. Wash the area with soap and water.

Note: If you accidentally removed too much GRANIX, contact your doctor before giving your injection.

3A Pinch skin

Use your free hand to firmly pinch the skin you previously cleaned.

3B Insert the needle at a 45 to 90 degree angle

Hold the body of the syringe between your thumb and index finger. Use a quick motion to fully insert the needle straight into the pinched skin at a 45 to 90 degree angle.
When the needle is inserted, you can release the pinched skin.

Do not hold or push on the plunger while inserting the needle into the skin.

3C Push the plunger down injecting all of the GRANIX

Use your finger to gently push down on the plunger. When the plunger head is as far down as it will go, and all of the GRANIX has been injected, remove the needle from the skin.

3D Dispose of used syringe

Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
• made of a heavy-duty plastic,
• can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
• upright and stable during use,
• leak-resistant, and
• properly labeled to warn of hazardous waste inside the container.
When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.
Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

3E Treat the injection site if needed and wash your hands
If you see drops of blood at the injection site, you can press a cotton ball or gauze over the injection site for several seconds to stop the bleeding.
Apply bandage, if needed.
When you are finished, wash your hands with soap and warm water and dry thoroughly with a clean towel.

4. Repeat the procedure with the second syringe (If dose is more than 0.8mL)
If your dose is more than 0.8mL:
• Follow instructions 3A through 3E for injecting.
• Choose a different site for your second injection. If you want to use the same part of your body, make sure the second injection site is at least 1 inch away from the first injection site.

Example of dosing for a 1.1mL dose:

1st Syringe: 0.8mL
2nd Syringe: 0.3mL

TROUBLESHOOTING
If you have problems performing this procedure, please contact your healthcare professional.