

Teva Pharmaceuticals Safe Needle Collection and Disposal Plan for GRANIX® (tbo-filgrastim)

Teva Pharmaceutical Industries Ltd. and Cephalon, Inc. (collectively “Teva Pharmaceuticals” or “Teva”) respectively the manufacturer and marketer of GRANIX® (tbo-filgrastim) injection, 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, are committed to ensuring that GRANIX patients have access to the information they need to keep themselves and their households safe and in compliance with local and state sharps disposal laws.

Teva educates patients regarding the importance of proper needle and syringe disposal through the dissemination of patient communication materials, readily available on the GRANIX websites, as well as through proper home administration training provided by the patient’s nurse or HCP prior to the patient’s first self-injection.

Information about proper sharps disposal is available through a number of key GRANIX® communications, including:

- GRANIX® Prescribing Information and Instructions for Use
- GRANIX® Patient Administration Video
- GRANIX® How to Administer GRANIX Patient Guide
- GRANIX Self-Administration Demo Kit
- GRANIX Patient Brochure
- GRANIXRX.com
- GRANIXHCP.com

In these GRANIX® communications, patients are cautioned against the reuse of needles or syringes and educated about safe disposal procedures. Patients are instructed to:

- Dispose of used needles and syringes into an FDA approved sharps container immediately after use and to not dispose of loose needles and syringes in household trash
- Dispose of used needles and syringes, *if patient does not have access to an FDA cleared sharps container*, into a household container that is made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-resistant lid, is upright and stable during use, leak resistant, and properly labeled to warn of hazardous waste inside the container
- Follow community guidelines for the right way to dispose of sharps disposal container as there may be state or local laws about how to throw away used needles and syringes. Patients are also directed to the FDA website (www.fda.gov/safesharpsdisposal) for state specific regulations
- Do not dispose of used sharps container in household trash, unless community guidelines permit this
- Do not recycle used sharps container

- Use each GRANIX[®] (tbo-filgrastim) injection syringe for only 1 injection and no earlier than 24 hours following the end of the last chemotherapy cycle
- Wash hands, when finished with injection and disposal procedures, with soap and warm water and dry thoroughly with a clean towel

GRANIX[®] is a prescription medication given to people with certain types of cancer (nonmyeloid malignancies) who are receiving chemotherapy that affects the bone marrow to decrease the length of time that certain white blood cells (neutrophils) are very low (severe neutropenia).

Important information about GRANIX[®]

What should I tell my doctor before I receive GRANIX?

Before you take GRANIX, tell your doctor if you have sickle cell anemia or other blood problems, plan to have bone scans or tests, are allergic to filgrastim (NEUPOGEN[®]) or pegfilgrastim (Neulasta[®]), or have any other medical conditions. It is not known if GRANIX will harm an unborn baby or passes into breast milk; tell your doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed.

What are the possible side effects of GRANIX?

- **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 injection 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 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.

You are encouraged to report any side effects of prescription drugs to the FDA.
Visit fda.gov/medwatch, or call 1-800-FDA-1088.

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