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Filgrastim Injection

pronounced as (fil gra' stim)

Notice:

Filgrastim injection, filgrastim-aafi injection, filgrastim-sndz injection, and tbo-filgrastim injection are biologic medications (medications made from living organisms). Biosimilar filgrastim-aafi injection, filgrastim-sndz injection, and tbo-filgrastim injection are highly similar to filgrastim injection and work the same way as filgrastim injection in the body. Therefore, the term filgrastim injection products will be used to represent these medications in this discussion.

Why is this medication prescribed?

Filgrastim injection products (Granix, Neupogen, Nivestym, Zarxio) are used to decrease the chance of infection in people who have non myeloid cancer (cancer that does not involve the bone marrow) and are receiving chemotherapy medications that may decrease the number of neutrophils (a type of blood cell needed to fight infection). Filgrastim injection products (Neupogen, Nivestym, Zarxio) are also used to help increase the number of white blood cells, and decrease the length of time with fever in people with acute myeloid leukemia (AML; a type of cancer of the white blood cells) who are receiving treatment with chemotherapy medications. Filgrastim injection products (Neupogen, Nivestym, Zarxio) are also used in people who are undergoing bone marrow transplants, in people who have severe chronic neutropenia (condition in which there are a low number of neutrophils in the blood), and to prepare the blood for leukapheresis (a treatment in which certain blood cells are removed from the body). Filgrastim injection (Neupogen) is also used to increase the chance of survival in people who have been exposed to harmful amounts of radiation, which can cause severe and life-threatening damage to your bone marrow. Filgrastim is in a class of medications called colony-stimulating factors. It works by helping the body make more neutrophils.

How should this medicine be used?

Filgrastim injection products come as a solution (liquid) in vials and prefilled syringes to inject under the skin or into a vein. It is usually given once a day, but filgrastim injection products (Neupogen, Nivestym, Zarxio) may be given twice a day when it is used to treat severe chronic neutropenia. The length of your treatment depends on the condition that you have and how well your body responds to the medication.

If you are using filgrastim injection products to decrease the risk of infection, decrease the time with fever, or increase the number of white blood cells during chemotherapy, you will receive your first dose of the medication at least 24 hours after you receive a dose of chemotherapy, and will continue to receive the medication every day for up to 2 weeks or until your blood cell counts return to normal. If you are using filgrastim injection products to decrease the risk of infection during a bone marrow transplant, you will receive the medication at least 24 hours after you receive chemotherapy and at least 24 hours after the bone marrow is infused. If you are using filgrastim injection products to prepare your blood for leukapheresis, you will receive your first dose at least 4 days before the first leukapheresis and will continue to receive the medication until the last leukapheresis. If you are using filgrastim injection products to treat severe chronic neutropenia, you may need to use the medication for a long period of time. If you are using filgrastim injection because you have been exposed to harmful amounts of radiation, your doctor will monitor you carefully and the length of your treatment will depend on how well your body responds to the medication. Do not stop using filgrastim injection products without talking to your doctor.

Filgrastim injection products may be given to you by a nurse or other healthcare provider, or you may be told to inject the medication under the skin at home. If you or a caregiver will be injecting filgrastim injection products at home, a healthcare provider will show you or your caregiver how to inject the medication. Be sure that you understand these directions. Ask your healthcare provider if you have any questions. Use filgrastim injection products exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Do not shake vials or syringes containing filgrastim solution. Always look at filgrastim injection products before injecting. Do not use if the expiration date has passed, or if the filgrastim solution has particles or looks foamy, cloudy, or discolored.

Use each syringe or vial only once. Even if there is still some solution left in the syringe or vial, do not use it again. Dispose of used needles, syringes, and vials in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

Your doctor may start you on a low dose of filgrastim injection products and gradually increase your dose. Your doctor may also decrease your dose, depending on how your body reacts to the medication.

If you are using filgrastim injection products to treat severe chronic neutropenia, you should know that this medication will control your condition but will not cure it. Continue to use filgrastim injection products even if you feel well. Do not stop using filgrastim injection products without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

Filgrastim injection products are also sometimes used to treat certain types of myelodysplastic syndrome (a group of conditions in which the bone marrow produces blood cells that are misshapen and does not produce enough healthy blood cells) and aplastic anemia (a condition in which the bone marrow does not make enough blood cells). Filgrastim injection products are also sometimes used to

decrease the chance of infection in people who have human immunodeficiency virus (HIV) or people who are taking certain medications that decrease the number of neutrophils. Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using filgrastim injection products,

- tell your doctor and pharmacist if you are allergic to filgrastim, pegfilgrastim (Neulasta), any other medications or any of the ingredients in filgrastim injection products. Also tell your doctor if you or the person who will be injecting filgrastim injection products (Neupogen, Zarxio) is allergic to latex.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you are being treated with radiation therapy and if you have or have ever had chronic myeloid leukemia (a slowly progressing disease in which too many white blood cells are made in the bone marrow), or myelodysplasia (problems with bone marrow cells that may develop into leukemia).
- tell your doctor if you have sickle cell disease (a blood disease that may cause painful crises, a low number of red blood cells, infection, and damage to the internal organs). If you have sickle cell disease, you may be more likely to have a crisis during your treatment with filgrastim injection products. Drink plenty of fluids during your treatment with filgrastim injection products and call your doctor right away if you have a sickle cell crisis during your treatment.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using filgrastim injection products call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using filgrastim injection products.
- you should know that filgrastim injection products decrease the risk of infection, but does not prevent all infections that may develop during or after chemotherapy. Call your doctor if you develop signs of infection such as fever; chills; rash; sore throat; diarrhea; or redness, swelling, or pain around a cut or sore.
- if you get filgrastim solution on your skin, wash the area with soap and water. If filgrastim solution gets in your eye, flush your eye thoroughly with water.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you will be injecting filgrastim injection product at home, talk to your doctor about what you should do if you forget to inject the medication on schedule.

What side effects can this medication cause?

Filgrastim injection products may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- redness, swelling, bruising, itching or a lump in the place where the medication was injected
- bone, joint, back, arm, leg, mouth, throat, or muscle pain
- headache
- rash
- constipation
- diarrhea
- nausea
- vomiting
- loss of appetite
- difficulty falling asleep or staying asleep
- decreased sense of touch
- hair loss
- nosebleeds
- tiredness, lack of energy
- feeling unwell
- dizziness

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- pain in the left upper part of the stomach or the tip of the left shoulder
- fever, shortness of breath, trouble breathing, fast breathing
- trouble breathing, coughing up blood
- fever, abdominal pain, back pain, feeling unwell
- swelling of stomach area or other swelling, decreased urination, trouble breathing, dizziness, tiredness
- rash, hives, itching, swelling of the face, eyes, or mouth, wheezing, shortness of breath
- unusual bleeding or bruising, purple markings under the skin, red skin
- decreased urination, dark or bloody urine, swelling of the face or ankles
- painful, urgent, or frequent urination

Some people who used filgrastim injection products to treat severe chronic neutropenia developed leukemia (cancer that starts in the bone marrow) or changes in the bone marrow cells that show that leukemia may develop in the future. People who have severe chronic neutropenia may develop leukemia even if they do not use filgrastim. There is not enough information to tell if filgrastim injection

products increase the chance that people with severe chronic neutropenia will develop leukemia. Talk to your doctor about the risks of using this medication.

Filgrastim injection products may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store filgrastim injection products in the refrigerator. If you accidentally freeze filgrastim (Neupogen, Nivestym, Zarxio), you may allow it to thaw in the refrigerator. However, if you freeze the same syringe or vial of filgrastim a second time, you should dispose of that syringe or vial. Filgrastim (Neupogen, Nivestym, Zarxio) may be kept at room temperature for up to 24 hours but should be kept away from direct sunlight. Filgrastim (Granix) may be stored in the freezer for up to 24 hours, or may be kept at room temperature for up to 5 days but should be protected from light.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to filgrastim injection products.

Before having a bone imaging study, tell your doctor and the technician that you are using filgrastim injection products. Filgrastim injection products may affect the results of this type of study.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Granix[®] (tbo-filgrastim)
- Neupogen[®] (filgrastim)

- Nivestym[®] (filgrastim-aafi)
- Zarxio[®] (filgrastim-sndz)

Other names

- Granulocyte Colony-Stimulating Factor

- G-CSF

- Recombinant Methionyl Human G-CSF

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