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Pegfilgrastim Injection

pronounced as (peg fil gra' stim)

Notice:

Pegfilgrastim injection, pegfilgrastim-bmez, pegfilgrastim-cbqv, and pegfilgrastim-jmdb injection are biologic medications (medications made from living organisms). Biosimilar pegfilgrastim-bmez, pegfilgrastim-cbqv, and pegfilgrastim-jmdb injection are highly similar to pegfilgrastim injection and work the same way as pegfilgrastim injection in the body. Therefore, the term pegfilgrastim injection products will be used to represent these medications in this discussion.

Why is this medication prescribed?

Pegfilgrastim injection products are used to reduce the chance of infection in people who have certain types of cancer and are receiving chemotherapy medications that may decrease the number of neutrophils (a type of blood cell needed to fight infection). Pegfilgrastim injection (Neulasta) 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 bone marrow. Pegfilgrastim 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?

Pegfilgrastim injection products come as a solution (liquid) in prefilled injection syringes to inject subcutaneously (under the skin), and in a prefilled automatic injection device (on-body injector) to apply to the skin. If you are using a pegfilgrastim injection product to decrease the risk of infection during chemotherapy, it is usually given as a single dose for each chemotherapy cycle, no sooner than 24 hours after the last dose of chemotherapy of the cycle is given and more than 14 days before beginning the next chemotherapy cycle. If you are using pegfilgrastim injection because you have been exposed to harmful amounts of radiation, it is usually given as 2 single doses, 1 week apart. Your doctor will tell you exactly when you should use pegfilgrastim injection products.

Pegfilgrastim injection products may be given to you by a nurse or other healthcare provider, you may be told to inject the medication yourself at home, or you may receive a prefilled automatic injection device by the nurse or healthcare provider that will inject the medication automatically for you at home. If you will be injecting pegfilgrastim injection products yourself at home, or if you receive the prefilled

automatic injection device, a healthcare provider will show you how to inject the medication, or how to manage the device. Your healthcare provider will also give you the manufacturer's information for the patient. Ask your healthcare provider to explain any part that you do not understand. Use a pegfilgrastim injection product exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

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

If your pegfilgrastim solution comes in a prefilled automatic injection device, the device will usually be applied to your abdomen or the back of your arm by a nurse or other healthcare provider the day before you will receive the dose of pegfilgrastim. The next day (approximately 27 hours after the prefilled automatic injection device was applied to your skin), the dose of pegfilgrastim solution will be automatically injected subcutaneously over 45 minutes.

When you have the pegfilgrastim prefilled automatic injection device in place;

- you should have a caregiver with you the first time you receive a dose of pegfilgrastim or anytime the prefilled automatic injection device is applied to the back of your arm.
- you will need to monitor the prefilled automatic injection device while the entire dose of pegfilgrastim is injected in your body, so you should avoid activities and being in places that may interfere with monitoring while you are receiving the dose of filgrastim and for 1 hour afterwards.
- you should not travel, drive a car, or operate machinery 1 hour before and 2 hours after you receive your dose of pegfilgrastim with the prefilled automatic injection device (about 26 to 29 hours after the it was applied).
- you should make sure that you keep the prefilled automatic injection device at least 4 inches away from electric appliances and equipment including cell phones, cordless telephones, and microwave ovens.
- you should avoid airport x-rays and request a manual pat down if you have to travel after the prefilled automatic injection device is applied to your body and before you receive your dose of pegfilgrastim.
- you should immediately remove the prefilled automatic injection device if you have an allergic reaction while you are receiving your dose of pegfilgrastim by grabbing the edge of the adhesive pad and peeling it off. Call your doctor immediately and get emergency medical treatment.
- you should call your doctor immediately if the prefilled automatic injection device comes off of your skin, if the adhesive becomes noticeably wet, if you see dripping from the device, or if the status light flashes red. You should keep the prefilled automatic injection device dry for 3 hours before you receive your dose of pegfilgrastim to help you notice if your device starts to leak while you are receiving your dose.
- you should avoid being exposed to medical imaging studies (X-ray scan, MRI, CT scan, ultrasound) or oxygen rich environments (hyperbaric chambers).
- you should avoid sleeping or applying pressure on the prefilled automatic injection device.
- you should avoid hot tubs, whirlpools, saunas, and direct sunlight.

- you should avoid using lotions, oils, creams, and cleansers on your skin near the prefilled automatic injection device.

If the prefilled automatic injection device flashes red, if the device comes off before the full dose is delivered, or if the adhesive on the device becomes wet or there is leaking, call your doctor right away. You may not have received the full dose of pegfilgrastim, and may need an additional dose.

Dispose of used needles, syringes, and devices in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

Other uses for this medicine

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

What special precautions should I follow?

Before using pegfilgrastim injection products,

- tell your doctor and pharmacist if you are allergic to pegfilgrastim, pegfilgrastim-bmez, pegfilgrastim-cbqv, pegfilgrastim-jmdb, filgrastim (Granix, Neupogen, Nivestym, Zarxio), any other medications, or any of the ingredients in pegfilgrastim injection products. Also tell your doctor if you or the person who will be injecting a pegfilgrastim injection product for you is allergic to latex or acrylic adhesives.
- 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 have or have ever had cancer of the blood or 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 a pegfilgrastim injection product. 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 a pegfilgrastim injection product, call your doctor.
- you should know that pegfilgrastim 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.

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 a pegfilgrastim 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?

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

- bone pain
- pain in arms or legs

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 your left shoulder
- fever, shortness of breath, trouble breathing, fast breathing
- swelling of the face, throat, or around the mouth or eyes, hives, rash, itching, trouble swallowing or breathing
- swelling of your face or ankles, bloody or dark colored urine, decreased urination
- fever, abdominal pain, back pain, feeling unwell
- swelling of stomach area or other swelling, decreased urination, trouble breathing, dizziness, tiredness

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

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

Keep this medication in the carton it came in, tightly closed, and out of reach of children. Store pegfilgrastim injection products in the refrigerator but do not freeze them. If you accidentally freeze the medication, you may allow it to thaw in the refrigerator. However, if you freeze the same syringe of medication a second time, you should dispose of that syringe. Pegfilgrastim injection products (Neulasta prefilled syringe, Udenyca) may be kept at room temperature for up to 48 hours, and pegfilgrastim injection (Fulphila) may be kept at room temperature for up to 72 hours. Pegfilgrastim injection products should be kept away from direct sunlight.

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.

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>]

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.

Symptoms of overdose may include the following:

- bone pain
- swelling
- shortness of breath

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 a pegfilgrastim injection product.

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

Do not let anyone else take 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

- Fulphila[®](pegfilgrastim-jmdb)
- Neulasta[®](pegfilgrastim)
- Udenyca[®](pegfilgrastim-cbqv)
- Ziextenzo (pegfilgrastim-bmez)

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