Patient Information
FYLNETRA® (fil-ne-trah)
(pegfilgrastim-pbbk)
injection
Single-Dose Prefilled Syringe

What is FYLNETRA?
FYLNETRA 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.

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

Before you receive FYLNETRA, tell your healthcare provider about all of your medical conditions, including if you:
- have a sickle cell disorder
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if FYLNETRA will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if FYLNETRA passes into your breast milk

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

How will I receive FYLNETRA?
- **FYLNETRA is given as an injection under your skin (subcutaneous injection) by a healthcare provider. If your healthcare provider decides that the subcutaneous injections can be given at home by you or your caregiver, follow the detailed "Instructions for Use" that comes with your FYLNETRA for information on how to prepare and inject a dose of FYLNETRA.**
- You and your caregiver will be shown how to prepare and inject FYLNETRA before you use it.
- You should not inject a dose of FYLNETRA to children weighing less than 45 kg from a FYLNETRA prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the FYLNETRA prefilled syringe.
- If you are receiving FYLNETRA because you are also receiving chemotherapy, the last dose of FYLNETRA should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of FYLNETRA, talk to your healthcare provider about when you should give your next dose.

What are the possible side effects of FYLNETRA?
FYLNETRA may cause serious side effects, including:
- **Spleen rupture.** Your spleen may become enlarged and can rupture. 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.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency 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.** FYLNETRA 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. If you have any of these symptoms, stop using FYLNETRA and call your healthcare provider or get emergency medical help right away.
- **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 FYLNETRA. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** FYLNETRA 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
  - you urinate less than usual
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with FYLNETRA.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with FYLNETRA. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with FYLNETRA. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.

- **Capillary Leak Syndrome.** FYLNETRA 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
- **Myelodysplastic syndrome and acute myeloid leukemia.** If you have breast cancer or lung cancer, when FYLNETRA 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 FYLNETRA.
- **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 pegfilgrastim products. Symptoms may include fever, abdominal pain, feeling tired, and back pain. Call your healthcare provider if you experience these symptoms.

The most common side effects of FYLNETRA are pain in the bones, arms, and legs.
These are not all the possible side effects of FYLNETRA.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FYLNETRA?

- Store FYLNETRA in the refrigerator between 36° F to 46° F (2° C to 8° C).
- **Do not** freeze.
- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Do not shake the prefilled syringe.
- Take FYLNETRA out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any FYLNETRA that has been left at room temperature, 68° F to 77° F (20° C to 25° C), for more than 72 hours.

Keep the FYLNETRA prefilled syringe out of the reach of children.

General information about the safe and effective use of FYLNETRA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use FYLNETRA for a condition for which it was not prescribed. Do not give FYLNETRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about FYLNETRA that is written for health professionals.

What are the ingredients in FYLNETRA?

Active ingredient: pegfilgrastim-pbbk

Inactive ingredients: acetic acid, polysorbate 20, sodium hydroxide and sorbitol in water for injection, USP.

Manufactured by: **Kashiv BioSciences, LLC,** Piscataway, NJ 08854

US License No. 2131

Distributed by: **Amneal Pharmaceuticals LLC,** Bridgewater, NJ 08807

For more information, go to www.fylnetra.us or call 1-877-835-5472.

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

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