

Patient Information Leaflet

 **Fulphila**[®]
 (pegfilgrastim-jmdb) injection

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What is FULPHILA®?

FULPHILA 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 FULPHILA

if you have had a serious allergic reaction to pegfilgrastim or filgrastim products.

Before you receive FULPHILA, tell your healthcare provider about all of your medical conditions, including if you:

- if you have a sickle cell disorder
- if you have kidney problems
- if you are pregnant or plan to become pregnant
- if you are breastfeeding or plan to breastfeed

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

What are possible side effects of FULPHILA?

FULPHILA, as other pegfilgrastims, 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 care right away if you have shortness of breath with or without a fever, trouble breathing, or a fast rate of breathing.
- **Serious allergic reactions.** FULPHILA 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 FULPHILA and call your healthcare provider or get emergency medical help right away.

- **Sickle cell crises.** You may have a serious sickle cell crisis if you have a sickle cell disorder and receive FULPHILA that can sometimes lead to death. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **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.** Your healthcare provider will check your blood during treatment with FULPHILA.
- **Decreased platelet count.** Your healthcare provider will check your blood during treatment with FULPHILA. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with FULPHILA. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Capillary Leak Syndrome.** FULPHILA can cause fluid to leak from blood vessels into your body's tissues. This condition is called "Capillary Leak Syndrome" and 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 FULPHILA 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 FULPHILA.

- **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 FULPHILA are pain in the bones, arms, and legs.

These are not all the possible side effects of FULPHILA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How will I receive FULPHILA?

- FULPHILA 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 FULPHILA for information on how to prepare and inject a dose of FULPHILA.
- You and your caregiver will be shown how to prepare and inject FULPHILA before you use it.
- You should not inject a dose of FULPHILA to children weighing less than 45 kg from a FULPHILA prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the FULPHILA prefilled syringe.
- If you are receiving FULPHILA because you are also receiving chemotherapy, the last dose of FULPHILA should be injected at least 14 days before and 24 hours after your dose of chemotherapy.
- If you miss a dose of FULPHILA, talk to your healthcare provider about when you should give your next dose.
- Keep the FULPHILA prefilled syringe

out of the reach of children.

How should I store FULPHILA?

- Store FULPHILA in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze.**
- Do not use a FULPHILA prefilled syringe that has been frozen more than 1 time
- Keep the prefilled syringe in the original carton to protect from light.
- Do not shake the prefilled syringe.
- Take FULPHILA out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any FULPHILA that has been left at room temperature, 68°F to 77°F (20°C to 25°C) for more than 72 hours or frozen more than 1 time.

General information about the safe and effective use of FULPHILA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use FULPHILA for a condition for which it was not prescribed.

Do not give FULPHILA 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 FULPHILA that is written for health professionals.

What are the ingredients in FULPHILA?

Active ingredient: pegfilgrastim-jmdb.
Inactive ingredients: acetate, D-sorbitol, polysorbate 20, and sodium in Water for Injection.

Please see accompanying [Full Prescribing Information](#).