

## Patient Information Leaflet

 **Fulphila**<sup>®</sup>  
(pegfilgrastim-jmdb) injection

Manufactured by: Mylan GmbH, Steinhausen,  
Switzerland, CH-6312 U.S.  
License No. 2062 Product of India.  
Code No.: KR/DRUGS/KTK/28D/7/2006  
Distributed by: Mylan Institutional LLC,  
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PEG-2019-0116

## 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:

- have a sickle cell disorder.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if Fulphila will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if pegfilgrastim 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.

## 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.

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

- **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, which could lead to death, if you have a sickle cell disorder and receive Fulphila. Call your healthcare provider right away if you have symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis).** Fulphila 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 Fulphila.
- **Capillary Leak Syndrome.** Fulphila 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

- **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.

## How should I store Fulphila?

- Store Fulphila 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 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.

**Keep the Fulphila prefilled syringe out of the reach of children.**

## 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.

OUTER VIEW



Patient Information Leaflet

Fulphila (pegfilgrastim-jmdb) injection



INNER VIEW



What is Fulphila?

Fulphila is a granulocyte colony-stimulating factor (G-CSF). It is used to increase the number of neutrophils, a type of white blood cell, produced in the bone marrow of your body.

Do not take Fulphila

If you have had a severe allergic reaction to pegfilgrastim or any of the ingredients.

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

- have a blood disorder
- have liver problems
- are pregnant or plan to become pregnant, if you are unsure, tell your healthcare provider
- are breastfeeding or plan to breastfeed, tell your healthcare provider
- are taking any other medicines, especially other granulocyte colony-stimulating factors.

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

What are possible side effects of Fulphila?

Fulphila, as other pegfilgrastim, may cause severe side effects, including:

- **Spleen rupture.** Tell your healthcare provider if you have had a splenic rupture. A ruptured spleen can cause death. Tell your healthcare provider right away if you find pain in the left upper abdominal area in your left shoulder.
- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Tell your healthcare provider if you have any difficulty breathing or you have any chest pain or cough. Tell your healthcare provider right away if you have any trouble breathing or a fast rate of breathing.

Other side effects include:

- **Severe allergic reactions.** Fulphila can cause allergic reactions. These reactions can cause a rash, hives, itching, dizziness, trouble breathing, wheezing, chest pain, swelling around your mouth or eyes, fast heart rate, and weakness. If you have any of these symptoms, stop using Fulphila and tell your healthcare provider right away. Emergency medical help might be needed.
- **Serious cell counts.** You may have a serious decrease in red, white, and platelet counts. If you have a decrease in any of these counts, tell your healthcare provider right away. If you have symptoms of blood cell counts such as pale or white stooling, an iron deficiency anemia, or other symptoms.
- **Acute myeloid leukemia (AML).** Fulphila can increase the risk of AML. Tell your healthcare provider right away if you develop any of the following symptoms:
  - feeling of your skin or when touched, pain
  - blood in your urine or stool
  - you are more tired than usual
- **Increased white blood cell count (leukocytosis).** Your healthcare provider will check your blood during treatment with Fulphila.
- **Quality of Life Symptoms.** Fulphila can cause you to feel tired, weak, or have a sore throat. Tell your healthcare provider if you have any of these symptoms. Tell your healthcare provider if you have any of the following symptoms:
  - feeling of your skin or when touched, pain
  - blood in your urine or stool
  - you are more tired than usual
  - feeling of your skin or when touched, pain
  - blood in your urine or stool
  - you are more tired than usual

The most common side effects of Fulphila are pain in the bone, arm, and back.

There are not all of the possible side effects of Fulphila.

Call your doctor for more information 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. Your healthcare provider will give you a single injection. Your healthcare provider will give you the injection in your upper arm. You will receive your injection for 1 day. You will receive your injection on the day you are hospitalized and expect a date of discharge.

Do not use your injection if you see any of the following:

- the solution is cloudy or has particles in it
- the solution is not clear
- the solution is not white or yellow
- the solution is not colorless

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Information about the white blood cells

White blood cells help fight off infections. Some white blood cells are called neutrophils. These white blood cells have been shown to be important in fighting off infections. Some people who receive Fulphila have experienced symptoms such as bone pain, back pain, and muscle pain. Call your healthcare provider if you experience these symptoms.

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How should I store Fulphila?

Store Fulphila at room temperature (20°C to 25°C / 68°F to 77°F). Do not freeze. Do not shake. Do not use if the solution is cloudy or has particles in it.

Keep the Fulphila out of the hands and eyes of children.

General information about the safe and effective use of Fulphila.

Medicines are sometimes compared to a scale. Some medicines are like a scale that is too heavy for you. Do not use Fulphila if you are too heavy for the scale.

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Information about the white blood cells

White blood cells help fight off infections. Some white blood cells are called neutrophils. These white blood cells have been shown to be important in fighting off infections. Some people who receive Fulphila have experienced symptoms such as bone pain, back pain, and muscle pain. Call your healthcare provider if you experience these symptoms.

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