PATIENT INFORMATION
ROLVEDON® (roll veh don)
(eflapegrastim-xnst)
injection

What is Rolvedon?
Rolvedon 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.

It is not known if Rolvedon is safe and effective in children.

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

Before receiving Rolvedon, 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 Rolvedon can harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with Rolvedon.
- are breastfeeding or plan to breastfeed. It is not known if Rolvedon passes into your breast milk.

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

How will I receive Rolvedon?
- Rolvedon 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 Rolvedon for information on how to prepare and inject a dose of Rolvedon.**
- You and your caregiver will be shown how to prepare and inject Rolvedon before you use it.
- You will receive 1 injection of Rolvedon for each cycle of chemotherapy.
- You will receive your injection of Rolvedon about **24 hours after you finish receiving your chemotherapy**.
- You should not receive Rolvedon for 14 days before or within 24 hours after your dose of chemotherapy.
- If you miss a dose of Rolvedon, talk to your healthcare provider about when you should receive your next dose.

What are the possible side effects of Rolvedon?

Rolvedon 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.** Rolvedon can cause serious allergic reactions. These reactions can cause a rash all 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 Rolvedon 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 Rolvedon. Call your healthcare provider right away if you develop symptoms of sickle cell crisis such as pain or difficulty breathing.
- **Kidney injury (glomerulonephritis)**. Rolvedon 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 count during treatment with Rolvedon.
- **Decreased platelet count (thrombocytopenia).** Your healthcare provider will check your blood during treatment with Rolvedon. Tell your healthcare provider if you have unusual bleeding or bruising during treatment with Rolvedon. This could be a sign of decreased platelet counts, which may reduce the ability of your blood to clot.
- **Capillary Leak Syndrome.** Rolvedon 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 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 Rolvedon 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 Rolvedon.
- **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 Rolvedon include:

- tiredness
- nausea
- diarrhea
- bone pain
- headache
- fever
- decreased red blood cell count
- rash
- muscle and joint pain
- back pain

These are not all the possible side effects of Rolvedon.

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

How should I store Rolvedon?

- Store Rolvedon in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze Rolvedon. Throw away (dispose of) any Rolvedon that has been frozen.
- Store Rolvedon in the original carton to protect from light.
- **Do not** shake Rolvedon.
- Take the carton out of the refrigerator and place the sealed blister tray on a clean flat surface for at least 30 minutes to allow it to reach room temperature before use.
- Throw away (dispose of) any Rolvedon that has been left at room temperature, 68ºF to 77ºF (20ºC to 25ºC), for more than 12 hours.

Keep Rolvedon and all medicines out of the reach of children.

General information about the safe and effective use of Rolvedon.

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

What are the ingredients in Rolvedon?

Active ingredient: eflapegrastim-xnst

Inactive ingredients: citric acid monohydrate, mannitol, polysorbate 80, and sodium chloride in Water for Injection. Sodium hydroxide may be used to adjust pH to 5.5 during manufacturing.

Manufactured by: Spectrum Pharmaceuticals, Inc. Lake Forest, IL 60045

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For more information, go to www.rolvedon.com or call 1-888-713-0688.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 11/2023