

Eflapegrastim-xnst (Rolvedon)

About This Drug

Eflapegrastim-xnst belongs to a class of medicines called granulocyte colony-stimulating factors (G-CSF). G-CSF helps the body make more white blood cells. White blood cells help fight infection in your body. This drug is given as an injection under the skin (subcutaneously).

Possible Side Effects

- Decrease in the number of red blood cells. This may make you feel more tired.
- Nausea
- Diarrhea (loose bowel movements)
- Tiredness
- Fever
- Muscle, bone, and joint pain
- Back pain
- Headache
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with eflapegrastim-xnst. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Enlargement and inflammation (swelling) of your spleen, which can very rarely rupture and be life-threatening. Signs of enlargement may be left-sided pain in your abdomen and/or shoulder.
- Trouble breathing because of fluid build-up in your lungs caused by inflammation (swelling) of the lungs
- Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Severe sickle cell crises can happen in patients with sickle cell disorders treated with eflapegrastim-xnst, which can be life-threatening.

- Changes in your kidney function
- A rapid increase in your white blood cells
- Decrease in the number of platelets. This may raise your risk of bleeding.
- A syndrome where fluid and protein can leak from your blood vessels into your tissues. This can cause a decrease in your blood protein level and blood pressure and fluid can accumulate in your tissues and/or lungs.
- Inflammation of the aorta - symptoms may include fever, abdominal pain, back pain, and feeling tired.
- Talk to your doctor about your risk of cancer. This drug may raise your risk of developing conditions such as myelodysplastic syndrome and acute leukemia.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

How to Take Your Medication

- Talk to your doctor, nurse, and/or pharmacist for proper preparation, dosing, and administration if you are self-injecting this medicine.
- Do not shake the medicine. You can take it out of the refrigerator 30 minutes before use to allow it to come to room temperature. Throw away any medicine that has been left at room temperature for longer than 12 hours.
- Do not reuse the needles, or any unused medicine left in the syringe after your dose is injected.
- **Missed dose:** If you miss a dose, contact your doctor right away.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- **Storage:** Store this medicine in the refrigerator between 36°F to 46°F (2°C to 8°C). Store this medicine in the original carton to protect it from light. Do not freeze. Throw away any medicine that has been frozen.
- **Disposal:** Discuss with your nurse or your doctor how to dispose of unused medicine/needles.

Treating Side Effects

- To decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Manage tiredness by pacing your activities for the day.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your doctor or nurse about medicine that is available to help stop or lessen diarrhea.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Drug Interactions

- There are no known interactions of eflapegrastim-xnst with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Easy bleeding or bruising
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Feeling dizzy or lightheaded
- Tiredness and/or weakness that interferes with your daily activities
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Severe pain in the left side of your abdomen and/or shoulder
- General pain, chest pain, and/or back pain that does not go away or is not relieved by prescribed medicine
- Decreased urine, very dark urine, or blood in your urine
- Foamy or bubbly-looking urine
- Swelling of the face, hands, feet, or any other part of the body



- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** It is not known if this drug may harm an unborn child. For this reason, be sure to talk with your doctor if you are pregnant or planning to become pregnant while receiving this drug. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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