



## Sargramostim Injection

(sar gram' oh stim)

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### **IMPORTANT WARNING:**

[Posted 01/24/2008; Selected revisions 6/25/08] Bayer and FDA informed healthcare professionals of the market withdrawal of the current liquid formulation of sargramostim (Leukine), a growth factor that helps fight infection and disease in appropriate patients by enhancing immune cell function. The product was withdrawn because of an upward trend in spontaneous reports of adverse reactions, including syncope (fainting), which are temporally correlated with a change in the formulation of liquid Leukine to include edetate disodium (EDTA). The upward trend in adverse reaction reporting rates has not been observed with the use of lyophilized Leukine.

Bayer has since reformulated liquid Leukine and this EDTA-free Leukine preparation is now available through normal distribution channels. Healthcare professionals should immediately stop using liquid Leukine preparations containing EDTA and return unused vials to the manufacturer. For more information visit the FDA website at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Leukine> and

[http://www.fda.gov/medwatch/safety/2008/Leukine\\_DHCP\\_01-23-2008.pdf](http://www.fda.gov/medwatch/safety/2008/Leukine_DHCP_01-23-2008.pdf) and the manufacturer's website at:

<http://www.leukine.com>.

### **About your treatment**

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Your doctor has ordered sargramostim to help your bone marrow make new white blood cells. The drug will be either given subcutaneously (beneath your skin) or added to an intravenous fluid that will drip through a needle or catheter placed in your vein for 2 hours once a day for 14-21 days.

Sargramostim is a synthetic version of substances naturally produced by your body. It helps you to fight infections so you can receive your next chemotherapy cycle as scheduled.

Your health care provider (doctor, nurse, or pharmacist) may measure the effectiveness and side effects of your treatment using laboratory tests and physical examinations. It is important to keep all appointments with your doctor and the laboratory. The length of treatment depends on how you respond to the medication.

### **Precautions**

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before administering sargramostim,

- tell your doctor and pharmacist if you are allergic to any drugs.
- tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially cancer chemotherapy medications, dexamethasone (Decadron), lithium (Lithobid), prednisone, zidovudine (AZT, Retrovir), and vitamins.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking sargramostim, call your doctor.

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### **Administering your medication**

Before you administer sargramostim, look at the solution closely. It should be clear and free of floating material. Observe the solution container to make sure there are no leaks. Do not use the solution if it is discolored, if it contains particles, or if the container leaks. Use a new solution, but show the damaged one to your health care provider.

It is important that you use your medication exactly as directed. Do not change your dosing schedule without talking to your health care provider. Patients with severe anemia often feel very tired and weak. Most patients start to feel better about 6 weeks after starting sargramostim. Do not stop your therapy on your own for any reason because your ability to avoid blood transfusions could be hampered.

### **Side effects**

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

The most common side effect during sargramostim therapy is mild bone pain, usually in the lower back or pelvis and lasting only a few days. Another common side effect is a flu-like syndrome with fever, fatigue, chills, and muscle aches. Your doctor may recommend that you take acetaminophen or other painkillers.

Tell your health care provider if any of these symptoms are severe or do not go away:

- headache

- diarrhea
- skin rash or itching
- weakness
- dizziness or faintness
- flushing of the face

If you experience any of the following symptoms, call your health care provider immediately:

- fever
- shortness of breath
- sudden weight gain
- swelling of the lower legs or feet

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

### ***Storing your medication***

- Your health care provider probably will give you a several-day supply of sargramostim at a time. Your health care provider may give you directions on how to prepare each dose. Store the vials in the refrigerator.
- Take your next dose from the refrigerator 1 hour before using it; place it in a clean, dry area to allow it to warm to room temperature.
- Avoid shaking the vial. Use a vial only once, and do not reenter a needle into a vial. Discard unused portions and outdated medication.
- Do not allow sargramostim to freeze.

Store your medication only as directed. Make sure you understand what you need to store your medication properly.

Keep your supplies in a clean, dry place when you are not using them, and keep all medications and supplies out of reach of children. Your health care provider will tell you how to throw away used needles, syringes, tubing, and containers to avoid accidental injury.

### ***In case of emergency/overdose***

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

### ***Signs of infection***

If you are receiving sargramostim in your vein or under your skin, you need to know the symptoms of a catheter-related infection (an infection where the needle enters your vein or skin). If you experience any of these effects near your intravenous catheter, tell your health care provider as soon as possible:

- tenderness
- warmth
- irritation
- drainage
- redness
- swelling
- pain

**Brand names**

- Leukine®

**Other names**

- GM-CSF

Last Revised - 04/01/2003