



Bayer HealthCare
Pharmaceuticals

Lyophilized Leukine Special Access Program Instructions

January 23, 2008 (updated January 24, 2008)

Dear U.S. Health Care Professionals:

Bayer HealthCare Pharmaceuticals, in consultation with the FDA, has decided to withdraw the current liquid formulation of Leukine® from the supply system. This decision was made in light of an upward trend in spontaneous reports of adverse reactions, including syncope (fainting), temporally correlated with liquid Leukine 500 mcg vial which currently contains EDTA (edetate disodium).

While Bayer works to increase supplies of lyophilized Leukine and reformulate the liquid Leukine (to eliminate EDTA), the lyophilized Leukine 250 mcg vial will be reserved for Leukine indications with benefits in life-threatening situations:

- patients following induction chemotherapy in acute myelogenous leukemia (AML), and
- patients with bone marrow transplantation engraftment failure or delay (BMT).

In addition, all patients currently on Leukine therapy in clinical studies will continue to have access to lyophilized Leukine through this special access program.

If lyophilized Leukine 250 mcg vials cannot be obtained through your current distribution channels, please take the following actions:

1. Physician completes a one page form indicating that he/she requires lyophilized Leukine 250 mcg vials for use in BMT or AML.
2. Physician submits the form via facsimile to Bayer Customer Service where it will be verified that the physician has confirmed that the product will be used for AML or BMT indications. The facsimile number is: 973-305-5388.
3. Bayer will then drop ship the order to the physician. Delivery should occur within one to two business days.

If you have questions regarding the liquid Leukine formulation withdrawal or the Leukine special access program for the lyophilized formulation, please call 1-888-84BAYER (1-888-842-2937).

Patient safety is Bayer's primary concern and we will continue to work closely with the FDA to restore US supplies of Leukine, using a non-EDTA formulation, as quickly as possible.

Regards,

A handwritten signature in black ink that reads "Jeff Humphrey, M.D.".

Jeff Humphrey, MD
Vice President, U.S. Medical Sciences, Oncology

Enclosure: Leukine Access Program Form