



Bayer HealthCare
Pharmaceuticals

US Market Withdrawal of Liquid Leukine 500 mcg vial

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). We request that you immediately stop using liquid Leukine 500 mcg vial and return any unused product. For your reference we have included a copy of the DHCP Letter that was posted on our websites.

Bayer has contracted with Capital Returns to facilitate the market withdrawal of the liquid Leukine formulation. Please note that Leukine is presently marketed under the Berlex Laboratories name. Bayer acquired Berlex in 2006 to form Bayer HealthCare Pharmaceuticals. We ask that you take the following actions:

1. Bayer has sent this notice to US physicians, hospitals, clinics, and wholesalers/distributors. You are not asked to contact any US customers or patients.
2. Carry out a physical count and record this data on the Business Reply Card. Mail the enclosed postage paid Business Reply Card – **even if you do not have the liquid Leukine 500 mcg vial in your inventory.**
3. If you have inventory, complete the enclosed Packing slip and return your stock of liquid Leukine 500 mcg vials using the enclosed prepaid UPS *Authorized Return Service*SM shipping labels to:

**Capital Returns, Inc.
6101 North 64th Street
Milwaukee, WI 53218**

Capital Returns will process your shipment. You will receive a refund from Bayer in 4 -6 weeks.

This formulation withdrawal extends to the wholesaler, pharmacy and physician levels. No other formulations of Leukine are being withdrawn from the market. For questions regarding liquid Leukine, please call Bayer HealthCare Pharmaceuticals toll-free at 1-888-84Bayer (1-888-842-2937).

This formulation withdrawal is being conducted with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience.

Regards,

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

Enclosures: Dear Healthcare Provider Letter;
Business Reply Card; Packing Slip and Shipping Labels