



A Public Entity

Inland Empire Health Plan

PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

January 31, 2012

FDA Medwatch Warning: Recall: Treanda (bendamustine)

This letter provides important new safety information regarding Treanda (bendamustine HCL). On 1/27/2012, Cephalon, Inc. notified healthcare professionals of a recall of:

Drug: Treanda (bendamustine HCL) for Injection 25mg/8mL

Lot No: TB30111

Expiration date: 12/2012

This product lot is being recalled due to the presence of particulate matter found in a single vial, which has been identified as glass fragments. Potential adverse events after intravenous administration of solutions containing particulates may present as an emboli and result in disruption of blood flow causing tissue/organ damage, especially in vulnerable patients such as those undergoing surgery, immunosuppressed individuals, and the elderly, as well as patients with micro or macrovascular disease, such as cardiac and renal disease, who may be more at risk since their vasculature and end organs are already compromised.

The affected Treanda lot is packaged in 8 mL vials and was distributed to wholesalers and distributors nationwide between March 22, 2011 and October 5, 2011. Recipients of the subject lot have been previously notified of this recall via overnight notification on 11/18/11. Wholesalers, retailers, hospitals and health care professionals who have lot TB30111 in their possession are instructed to immediately cease using the product and immediately quarantine product for return. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

More information can be found at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm289521.htm?source=govdelivery>

303 E. Vanderbilt Way, San Bernardino, CA 92408
Tel (909) 890-2049 Fax (909) 890-2058

Visit our web site at: www.iehp.org

A Public Entity