Sun Pharmaceutical Industries, Inc. (Sun Pharma) Initiates Voluntary U.S. Nationwide Recall of **DOXOrubicin Hydrochloride Liposome Injection 50mg/25 mL** Due To Potential Presence of Glass Particles

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FOR IMMEDIATE RELEASE MUMBAI, INDIA and PRINCETON, NJ - May 13, 2026 – Sun Pharma is voluntarily recalling within the U.S. to the hospital/user level, one batch of DOXOrubicin Hydrochloride Liposome Injection 50mg/25 mL, Lot # HAG2581B, Expiration 05/2027 (675 vials). The single batch of 675 vials is being recalled due to the detection of glass particles in some vials during production.

If glass particles are administered intravenously, they may pose a risk to patient safety including local irritation or swelling in response to the foreign material. More serious potential risks could include blockage of blood vessels and life-threatening blood clot events. To date, Sun Pharma has not received any reports of adverse events related to this batch. Sun Pharma has thoroughly investigated the source of the problem and has taken corrective and preventative actions.

Doxorubicin Hydrochloride Liposome Injection is indicated for Ovarian cancer, AIDS Related Kaposi Sarcoma and Multiple Myeloma. The product is packaged in translucent, red liposomal dispersion in 25 mL glass, single-dose vials for NDC 72603-200-01. The affected DOXOrubicin Hydrochloride Liposome Injection batch is Batch HAG2581B, Expiration 05/31/2027. The product can be identified by the label (Aisling Label), each vial is labeled to indicate the name of the product: DOXOrubicin Hydrochloride Liposome Injection 50mg/25 mL, NDC 72603-200-01 Lot# HAG2581B, Expiration 05/31/2027.

Sun Pharma is notifying its distributor and customers by express overnight mail and is arranging for return/replacement etc. of all recalled products.

Distributors/retailers/hospitals/users that have the product should stop using and return to place of purchase or discard the product. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or

using this drug product. To report suspected adverse events contact NorthStar Rx LLC at 1-800-206-7821.

Customers with questions regarding this recall can contact **Inmar Inc.,** (Sun Pharma's recall processor) by 855-745-9357**,** Monday through Friday between 8:30 am and 5:00 pm, U.S. Eastern Time, or via rxrecalls@inmar.com.

Inmar, Inc.

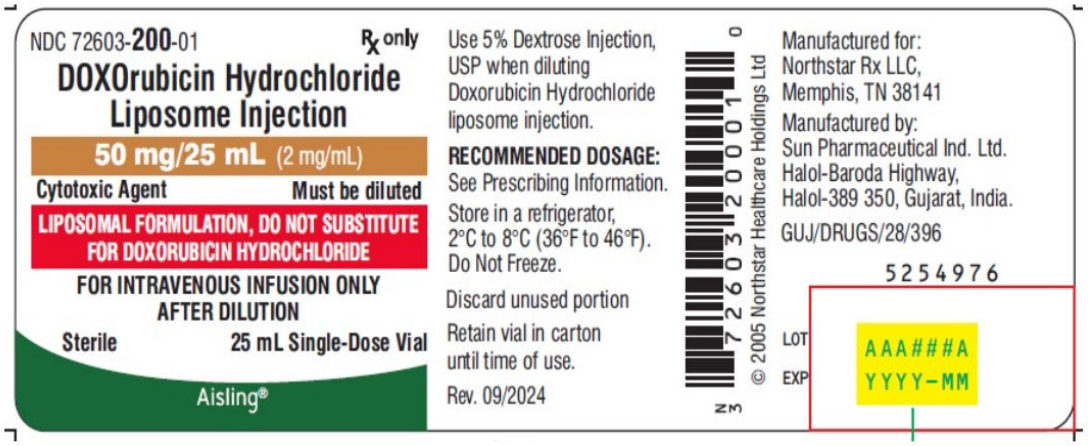
3845 Grand Lakes Way
Grand Prairie, TX 75050
Tel. 855-745-9357
Fax. 817-868-5362
Email: rxrecalls@inmar.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm[1]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Picture of the recalled Product



About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)
Sun Pharma is the world's leading specialty generics company with a presence in Innovative Medicines, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as Global Emerging Markets. Sun's high growth Innovative Medicines portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for about 20% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on LinkedIn & X (formerly Twitter).

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