IDArubicin Hydrochloride Injection Recall Alert

Date of Notice: March 29, 2022

Brief Description of Recall Alert

Teva Pharmaceuticals has initiated a voluntary nationwide recall of one (1) lot of IDArubicin Hydrochloride Injection USP 5 mg/5 mL vial, to the user level in the United States. This voluntary recall is initiated based on an internal inspection that found particulate matter in one (1) vial of the product identified as silica and iron oxide. No other vials have been observed to contain this defect. To date, Teva has received no product quality complaints or adverse event reports of this nature for the subject recall lot.

The administration of an injectable product that contains particulate matter may result in local irritation or swelling in response to the foreign material. If the particulate matter reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. While the health hazard risk could be severe if particulate matter is infused, Teva's internal health assessment determined that the likelihood of patient harm is remote or unlikely

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
IDArubicin Hydrochloride Injection, USP 5 mg/5 mL vial	0703-4154-11	31329657B	August 2023

Prescriber Information

Teva has notified its customers on March 28, 2022 and asked that the lot be recalled and to make arrangements for impacted product to be returned. Instructions for returning recalled product and crediting are given in the recall letter released by Teva.

For medical-related questions or to report an adverse event:

- Contact Medical Information at: 888-838-2872, option 3, then option 4
  - Live calls received: Monday - Friday, 9:00 AM - 5:00 PM Eastern Time;
  - Voicemail: 24 hours/day, 7 days/week;
- By email at: druginfo@tevapharm.com.

For product quality complaint-related questions:

- Contact Quality Assurance Services: 888-838-2872, option 4
  - Live calls received: Monday - Friday, 9:00 AM - 5:00 PM Eastern Time;
  - Voicemail: 24 hours/day, 7 days/week;

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
- Regular Mail or Fax: Download form 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

Member Information

Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Members with medical-related questions, who wish to report an adverse event or quality issues about the product being recalled, should contact Teva Medical Information at 1-888-838-2872 or druginfo@tevapharm.com, Monday through Friday 24 hours per day, 7 days per week.

RxAdvance Response

Members should continue taking IDArubicin hydrochloride injection until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.