URGENT DRUG RECALL

IDArubicin Hydrochloride Injection USP 5 mg/5 mL

INITIATED 03/29/2022

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling one lot of IDArubicin Hydrochloride Injection USP 5 mg/5 mL vial to the User Level.

Vial/Carton NDC	Lot #	Exp. Date	Size
0703-4154-11	31329657B	08/2023	5 mg/5 mL (1 mg/mL) 5 mL Single Dose Vial

The above lot in this recall was distributed from 12-04-2020 through 08-18-2021 under the label for Teva Pharmaceuticals USA, Inc.

This recall is being initiated because a foreign particle was observed in one (1) vial during a reserve sample inspection. 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.

This recall is being made with the knowledge of the Food and Drug Administration.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for lot # 31329657B**.**
- Immediately discontinue distribution of lot # 31329657B.
- **If you have further distributed lot # 31329657B, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form (SRF) as a basis for your SUB-RECALL letter.**
- Even if you have **no** product to return, promptly complete the attached recall SRF and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator:

  Inmar, 635 Vine Street, Winston Salem, NC 27101
  Email address: **rxrecalls@inmar.com**
  FAX: 817-868-5362

Inmar will send labels for Return Goods Authorization (RGA) and shipping after receipt of your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns and Stock Response Forms: Contact Inmar at: 855-319-5721 (dedicated phone line). Hours of Operation: M – F, 9.00 AM to 5.00 PM Eastern Time Recall Stock Response Forms - Contact Inmar at 855-319-5721 or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com.
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name:	
*DEA #:	Debit Memo #

**DEA # is required; in order to process your form.*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Vial/Carton NDC	Lot #	Quantity to Return (Vials)
0703-4154-11	31329657B	

Additional Stock Response Forms included: ***Yes*** ☐ ***No*** ☐

I have checked my stock and:

I **do not** have stock of the recalled item(s) **OR**

I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name):	DEA #*:
****DEA # is required; in order to process your form.***	
City:	State:

Please promptly return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B