



Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL
Norepinephrine Bitartrate Injection USP 1mg/mL
INITIATED 12/31/2021

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is initiating a voluntary recall of lot # 100020800 of Norepinephrine Bitartrate Injection USP 1mg/mL (4 mg/4 mL) to the RETAIL LEVEL. Detailed information on lot # 100020800 is given in the table below.

| Carton NDC | Vial NDC | Lot # | Exp. Date | Distribution Dates | Package Description | QTY Distributed |
|--------------|--------------|-----------|-----------|-------------------------|---------------------|-----------------|
| 0703-1153-03 | 0703-1153-01 | 100020800 | 07-2022 | 06/03/2021 – 06/22/2021 | 10 in 1 CARTON | 11,450 |

This recall is being initiated because of potential risks related to microbial recoveries found during historical assessments of Environmental Monitoring results in aseptic areas of manufacturing. It is important to note that at the time of commercial release, the lot in this recall met all test specification, including both sterility and endotoxin. Based on available data to date, there is no indication of product quality and sterility failure of the products in this recall. As such, the Health Hazard Assessment concluded that the likelihood of an adverse event is remote. If by a remote chance a patient is exposed to a product with compromised sterility, the potential for serious adverse health consequences could occur for individuals predisposed to develop opportunistic infections. To date, Teva has not received any product quality complaints or adverse event reports related to sterility of these products.

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 the recalled product lot **and** discontinue distribution.
- Immediately discontinue distribution of the specified product lot affected by this recall.
- **If you have further distributed this lot, 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 the dedicated phone line: 855-247-7503. Hours of Operation: M– F, 9.00 AM to 5.00 PM Eastern Time Recall Stock Response Forms - Contact Inmar at 855-247-7503 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 |
| 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 #: _____

Additional Stock Response Forms included: Yes ☐ No ☐

| Carton NDC | Vial NDC | Lot # | Quantity to Return (Vials) |
|--------------|--------------|-----------|----------------------------|
| 0703-1153-03 | 0703-1153-01 | 100020800 | |

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 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.**

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