

Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 4/27/16

Linezolid Injection 600 mg/300 mL

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Single Use Container Size	NDC# single use containers	NDC# box of 10 single use containers
2520715	7/2017	300 mL	0703-9060-31	0703-9060-33

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Linezolid Injection 600 mg/300 mL** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** due to the potential for leaking bags. A review of all adverse event reports involving the affected lot of linezolid concluded that the discovery of leaking linezolid infusion bags does not present a risk to patients and the risk of patient exposure to leaking infusion bags of linezolid is highly remote.

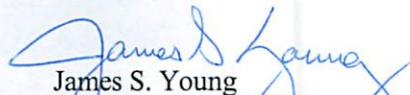
Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Linezolid Injection 600 mg/300 mL**.
- Our records indicate we shipped this product between December 3, 2015 and December 16, 2015.
- Immediately discontinue distribution of the specific lot being recalled.
- **Please perform a SUB-RECALL to your retail accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: rxrecalls@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800. For medical-related questions please contact Medical Information at 888-838-2872, option 3, then, option 4. For product complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,



James S. Young
Director, Quality Systems & Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals, USA Inc.

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Linezolid Injection 600 mg/300 mL

STOCK RESPONSE FORM

Please fill out completely

Date: _____

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

Customer/Store Name: _____ **DEA #:** _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ **State:** _____ **Zip:** _____

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

Lot #	Exp. Date	Single Use Container Size	Quantity to Return # of single use containers NDC# 0703-9060-31	Quantity to Return # of cartons of 10 single use containers NDC# 0703-9060-33
2520715	7/2017	300 mL		

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 #:** _____

City: _____ **State:** _____

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800

Medical-related questions - contact Medical Information at 888-838-2872, option 3, then, option 4.

Product complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3.

Please fax this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com

Inmar/MedTurn Use Only: _____

Scan	Labels	Store	Kit	D.B
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