

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 8/12/13

Carboplatin Injection, 10 mg / 1 mL (60mL vial)

MANUFACTURED BY:
Teva Parenteral Medicines, Inc.
Irvine, CA 92618

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

Lot #	Exp Date	Fill Size	NDC #
31314458B	8/2014	600mg/ 60mL	0703-3249-11
31314459B	8/2014	600mg/ 60mL	0703-3249-11
31315794B	10/2014	600mg/ 60mL	0703-3249-11
31315982B	11/2014	600mg/ 60mL	0703-3249-11

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Carboplatin Injection, 10 mg / 1 mL (60mL vial)** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** due to not meeting the required reduction of endotoxin during the annual revalidation of the vial washer. The health hazard assessment indicated potential adverse consequence of residual endotoxin in the vials could be serious; however, the patients using this product are under care of Medical oncologists who are familiar with the management of fever or neutropenic fever. Therefore, there is a low probability of moderate adverse health effects that could occur in rare cases.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Carboplatin Injection, 10 mg / 1 mL (60mL vial)**
- Our records indicate we shipped these lots between April 10, 2013 and April 11, 2013.
- Immediately discontinue distribution of the specific lots 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: recallnotice@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 Affairs at 888-838-2872, option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,



Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

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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	NDC #	Quantity to Return (# vials)
31314458B	8/2014	0703-3249-11	
31314459B	8/2014	0703-3249-11	
31315794B	10/2014	0703-3249-11	
31315982B	11/2014	0703-3249-11	

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 Services at 800-545-8800

Medical related questions - contact Medical Affairs at 888-838-2872, option 9

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

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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