

**Barr / Duramed Pharmaceuticals / (Teva Pharmaceuticals USA Inc.)**

**URGENT MEDICAL DEVICE RECALL – RETAIL LEVEL**

**Initiated 3/30/2012**

**ViaSpan Cold Storage Solution 1000mL Bag**

**MANUFACTURED BY:**  
Fresenius Kabi (Barr / Duramed Pharmaceuticals)  
Graz, Austria

**RECALLED BY:**  
Teva Pharmaceuticals USA  
Sellersville, PA 18960

Lot #	Exp. Date	Product Code	Size
16EK0007	10/2012	1000-46-06	10 x 1000mL Bags
16EK0193	10/2012	1000-46-06	10 x 1000mL Bags

Dear Customer:

Teva Pharmaceuticals USA Inc. is voluntarily recalling the above mentioned lots of **ViaSpan Cold Storage Solution Bags** distributed under the **Barr/Duramed Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** as a precautionary measure due to a lack of assurance of sterility.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the above lots of **ViaSpan Cold Storage Solution Bags**.
- Our records indicate we shipped this product between December 1, 2011 and March 19, 2012.
- 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](mailto: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 Services at 800-545-8800. Medical related questions, please contact Teva Medical Affairs at 215-641-6974. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from [clsnetlink.com](http://clsnetlink.com).

Sincerely,



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

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**ViaSpan Cold Storage Solution 1000mL Bag**

**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	Product Code	Size	QTY to Return (# Bags – count partial as 1)
16EK0007	10/2012	1000-46-06	10 x 1000mL Bags	
16EK0193	10/2012	1000-46-06	10 x 1000 mL Bags	

**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 Teva Medical Affairs 215-641-6974

Please fax this form to: 817-868-5362 or E-mail at: [recallnotice@inmar.com](mailto:recallnotice@inmar.com)

Inmar/MedTurn Use Only: \_\_\_\_\_

Scan	Labels	Store	Kit	D.B
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