

Teva Pharmaceuticals USA Inc.

URGENT RECALL – RETAIL LEVEL – INITIATED 2/8/2013

Tev-Tropin® (Somatropin (rDNA origin for injection)), TJet® Needle-Free Head A

Lot #	Exp Date	NDC #	Size
201131320087	9/2015	57844-336-85	15 units per carton

Medfusion RX (Briova RX)
1100 Lee Branch
Birmingham, AL 35242

Dear Pharmacy:

Ferring Pharmaceuticals, Inc. has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lot of **Tev-Tropin® (Somatropin (rDNA origin for injection)), TJet® Needle-Free Head A** distributed under the Teva label. This sub-recall is being carried out to Medfusion RX (Briova RX) due to some units being packaged in cartons labeled for Needle-Free Head B.

Please perform the following activities:

- Please examine your inventory immediately for the specified lot of **Tev-Tropin® (Somatropin (rDNA origin for injection)), TJet® Needle-Free Head A**.
- Our records indicate we shipped this product on December 13, 2012.
- Immediately discontinue distribution of the product lot being recalled.
- 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.

The completed Recall Stock Response form 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 sub-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 questions, please contact Growth Solutions® at 1-866-TEV-TROP (1-866-838-8767).

Sincerely,



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

Teva Pharmaceuticals USA Inc.

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Stock Response Form

Tev-Tropin[®] (Somatropin (rDNA origin for injection)), TJet[®] Needle-Free Head A

Lot #	Exp Date	NDC #	Qty to return (Single Unit)	Qty to return (Carton of 15)
201131320087	9/2015	57844-336-85		

Please fill out completely:

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 #: _____

Customers who did not purchase the product directly from the Manufacturer must complete the following.

Purchased From: Name _____ DEA #: _____

Address: _____

City: _____ State: _____ Zip: _____

I have checked my stock and: _____ I do not have any stock of the recalled items, **OR**

I have quarantined and listed in the stock response form the quantity of units of **Tev-Tropin[®] (Somatropin (rDNA origin for injection)), TJet[®] Needle-Free Head A** and will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue a recall return authorization and shipping label(s) _____ (please indicate the # of box labels needed)

Inquiries regarding this sub-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 or Medical related questions - contact Growth Solutions[®] at 1-866-TEV-TROP(1-866-838-8767).

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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