

GATE Pharmaceuticals / Teva Pharmaceuticals USA, Inc.

***AMENDED letter with updated instructions**

URGENT RECALL – RETAIL LEVEL – AMENDED 4/30/2014

Tev-Tropin[®] (Somatropin (rDNA origin) for injection)

MANUFACTURED FOR:

Gate Pharmaceuticals, Division of
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

RECALLED BY:

Ferring Pharmaceuticals Inc.
Parsippany, NJ 07054

Lot #	Exp Date	NDC #	Size
H11599A	03/2016	57844-713-19/ 57844-713-46	5mg Vial
H11599B	03/2016	57844-713-19/ 57844-713-46	5mg Vial
H12913A	05/2016	57844-713-19/ 57844-713-46	5mg Vial
H12913B	05/2016	57844-713-19/ 57844-713-46	5mg Vial
H12914A	05/2016	57844-713-19/ 57844-713-46	5mg Vial
H12914B	05/2016	57844-713-19/ 57844-713-46	5mg Vial
H13846A	07/2016	57844-713-19/ 57844-713-46	5mg Vial
H13846B	07/2016	57844-713-19/ 57844-713-46	5mg Vial

Dear Customer:

Ferring Pharmaceuticals, Inc. has notified GATE Pharmaceuticals, a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lots of **Tev-Tropin[®] (Somatropin (rDNA origin) for injection)** distributed under the **GATE Pharmaceuticals label**. This sub-recall is being carried out to the **RETAIL LEVEL** because these lots of Drug Product were manufactured with batches of drug substance that were determined to contain the presence of silicone oil as the result of a coolant line leak during manufacture. Investigation has determined that there is no adverse health risk associated with this event.

Please perform the following activities:

- Please examine your inventory immediately for the specified lots of **Tev-Tropin[®] (Somatropin (rDNA origin) for injection)**.
- Our records indicate we shipped this product from September 19, 2013 to January 22, 2014.
- Immediately discontinue distribution of the product lots being recalled.
- ***Please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form. Note: NDC# 57844-713-19 contains one 5mg vial and one diluent vial. NDC# 57844-713-46 is for the 5mg vial only.**
- 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). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Con H Lee FOR DAVID ROBERTS.

David L. Roberts
Director, Quality Systems
Teva Pharmaceuticals USA, Inc.

GATE Pharmaceuticals / Teva Pharmaceuticals USA, Inc.

URGENT RECALL – RETAIL LEVEL – INITIATED 4/29/2014
Stock Response Form

Tev-Tropin® (Somatropin (rDNA origin) for injection)

Lot #	Exp Date	NDC #	Qty to return (Vials)
H11599A	03/2016	57844-713-19/ 57844-713-46	
H11599B	03/2016	57844-713-19/ 57844-713-46	
H12913A	05/2016	57844-713-19/ 57844-713-46	
H12913B	05/2016	57844-713-19/ 57844-713-46	
H12914A	05/2016	57844-713-19/ 57844-713-46	
H12914B	05/2016	57844-713-19/ 57844-713-46	
H13846A	07/2016	57844-713-19/ 57844-713-46	
H13846B	07/2016	57844-713-19/ 57844-713-46	

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)**, 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

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