URGENT DRUG RECALL

Testosterone Gel 1%, CIII, 25 mg/2.5 g

INITIATED 06/29/2022

Teva Pharmaceuticals USA, Inc.

Carton NDC (30 packets in 1 carton)	Packet NDC	Lot Number	Expiration Date
0591-3216-30	0591-3216-17	1403180	10/2022

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the one lot of Testosterone Gel 1% CIII 25 mg/2.5 g per unit dose, for topical use, to the RETAIL LEVEL, which was distributed nationwide under the Actavis Pharma Inc., label.

This recall is being initiated because an out of specification assay result was obtained during stability testing. Specifically, the product may have slightly higher concentrations of testosterone. The main safety concern that may arise from a slightly higher assay limit for testosterone is a higher risk of experiencing adverse events associated with testosterone replacement therapy. Teva's health hazard assessment concluded that use of product of concern might lead to moderate adverse events. Common adverse events associated with testosterone replacement therapy include application site reactions (e.g. skin irritation), acne, lab tests changes (e.g., elevated hemoglobin or hematocrit, elevated triglycerides, hyperlipidemia, etc.), and elevated prostate specific antigen (PSA). Patients with benign prostatic hyperplasia (BPH) treated with androgens are at increased risk for worsening signs and symptoms of BPH.

This recall is being made with the knowledge of the Food and Drug Administration.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for lot # 1403180 of Testosterone Gel 1% CIII and discontinue distribution.
- Teva USA shipped lot # 1403180 to its direct customers from 02/17/2021 through 04/07/2021.
- Even if you have **no** product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

  Inmar, 635 Vine Street, Winston Salem, NC 27101.
  Email address: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

- **If you have further distributed lot # 1403180 of Testosterone Gel 1% CIII, please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

Inmar will send a Return Goods Authorization label, 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 a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns and Recall Stock Response Forms: Contact Inmar at: 855-898-9827 or acquire forms from clsnetlink.com. Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Date: _____

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

Customer/Store Name:	
*DEA #:	*Debit Memo #

DEA # is required in order to process your form.

Address: _____

City: _____ State: _____ Zip: _____

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

Carton NDC (30 packets in 1 carton)	Packet NDC	Lot Number	Expiration Date	Quantity to Return *(For Full Cartons of 30 packets)*	Quantity to Return *(For Individual Packets in Partial Cartons)*
0591-3216-30	0591-3216-17	1403180	10/2022		

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 #: _____

DEA # is required; in order to process your form.

City: _____ State: _____

Please return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B