URGENT DRUG RECALL
Testosterone Gel, 1.62% 1.25 grams, CIII
August 08, 2024

Teva Pharmaceuticals USA, Inc.

Testosterone Gel, 1.62% 1.25 grams, CIII, for topical use				
Carton NDC	Packet NDC	Lot #	Exp. Date	Size
0591-2925-30	0591-2925-32	100042386	06/2025	30 packets/carton

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA) is initiating a voluntary nationwide recall of *one lot* of **Testosterone Gel, 1.62% 1.25 grams, CIII, for topical use,** to the **RETAIL LEVEL.** The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is the 12-month stability test result for assay are above the specification limit for lot 100042386. The clinical concern is a risk for patients experiencing adverse events associated with testosterone replacement therapy. Nonetheless, patients are expected to be monitored by their treating physician to ensure proper dosing through the entire treatment period, including monitoring of testosterone levels thus allowing for dose adjustments according to the patient's needs. TEVA has not received any product quality complaints related to this lot. Teva's health hazard assessment concluded that use of the recalled lot could result in moderate adverse events while the likelihood of the harm is remote and overall risk of harm in patient population is low.

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

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the specified recall lot 100042386.
- Immediately discontinue distribution of and quarantine the specified lot 100042386 being recalled.
- TEVA's records indicate that the recalled lot 100042386 was commercially distributed/shipped to its direct customers from 08/22/2023 through 10/26/2023.
- **If you have further distributed the recall lot, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF to Inmar, Attn: Recall Coordinator by any one of these means:

  MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Appropriate credit for your product returns, plus expenses for handling and shipping, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA will 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: Contact Inmar at 877-896-3978 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva 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 or by email at QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 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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RECALL BUSINESS REPLY FORM

Date Form Completed _____

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One):

☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations? ☐ YES ☐ NO

Did you communicate the recalls to your direct accounts ☐ YES ☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from: _____
Name of Your Wholesaler/Distributor and Location

Section 2 – Quantity of Product to Return

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

Carton NDC	Packet NDC	Size	Lot #	# of Cartons to Return *(Count Partials as 1)*
0591-2925-30	0591-2925-32	100042386	06/2025	

Please indicate the number of shipping labels that you need to return the recalled product(s): _____

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