



Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL

Testosterone Gel 1% CIII

INITIATED 11/11/2020

Carton NDC (30 packets in 1 carton)	Packet NDC	Lot Number	Expiration Date
0591-3216-30	0591-3216-17	1351104	08/2021

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of Testosterone Gel 1% CIII to the RETAIL LEVEL, which was distributed under the Actavis Pharma Inc., label.

This recall is being initiated because out of specification assay result was obtained during stability testing. Specifically, the product may have higher concentrations of testosterone. Based on the health hazard assessment, use of product may lead to moderate adverse events. However, the likelihood of occurrence is remote and the overall risk of harm is low.

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 the above specified lot of Testosterone Gel 1% CIII and discontinue distribution.
- Our records indicate Teva USA shipped the lot to its customers from December 20, 2019 through February 4, 2020.
- **If you have further distributed the lot, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.**
- 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.

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: Contact Inmar at: 855-634-0456. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at: 855-634-0456 or acquire forms from clsnetlink.com .
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.



Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Please fill out completely

Date: _____

DIRECT CUSTOMERS ONLY: Does this response include all DC locations?

☐ YES

☐ NO

Customer/Store Name: _____ DEA #: _____

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

Address: _____

City: _____ State: _____ Zip: _____

Contact Name Telephone #:
(please print):

Carton NDC	Packet NDC	Lot Number	Exp, Date	Quantity to Return (Full Carton of 30 packets)	Quantity to Return (Partial Cartons)
0591-3216-30	0591-3216-17	1351104	08/2021		

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: _____

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