URGENT DRUG RECALL
Alprostadil Injection USP 500 mcg/mL
Initiated 05/18/2022

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling two lots of Alprostadil Injection USP 500 mcg/mL to the Retail/Institutional Level. Detailed information for these lots are given in the table below.

The lots in this recall were distributed from 06/09/2021 through 04/12/2022 under the label for Teva Pharmaceuticals USA, Inc.

Shelf Pack NDC	Vial NDC	Lot #	Exp. Date	Size	Strength
0703-1501-02	0703-1501-01	100022404	10/2022	1 mL Single Dose Vial 5 Vials per Shelf Pack	500 mcg/mL
0703-1501-02	0703-1501-01	100023333	12/2022	1 mL Single Dose Vial 5 Vials per Shelf Pack	500 mcg/mL

This recall is being initiated because of an out-of-specification (OOS) result found in annual stability testing of a lot at the end of its shelf life (The OOS lot is not included in this recall since it is expired). Specifically, an OOS result of 6.6% (specification limit: 5.0%) was obtained for a known degradation impurity (i.e., Prostaglandin-A1 or PGA_1) of the active ingredient Alprostadil (also known as Prostaglandin-E1 or PGE_1). While current analysis of the lots in this recall are within specification limits, including the limits for the PGA_1 degradant, the annual stability of these lots are currently trending to become OOS for PGA_1 before the end of their respective shelf life.

Teva's Toxicological assessment concluded that there is no extra toxicological risk to the patient from exceeding the specification limit of NMT 5.0% for PGA_1 in Alprostadil drug product up to 6.6%. It should be noted that the active ingredient PGE_1 and its known degradant, PGA_1, are well-known endogenous substances. Moreover, PGA_1 is also a metabolite of PGE_1 active ingredient. Based on available data, Teva's internal health assessment determined the exposure to the product of concern is not expected to lead to any adverse health consequences.

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

- Immediately examine your inventory for the two lot numbers: 100022404 and 100023333**.**
- Immediately discontinue distribution of the two lot numbers: 100022404 and 100023333.
- **If you have further distributed the two lot numbers 100022404 and 100023333, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form (SRF) as a basis for your SUB-RECALL letter.**
- Promptly complete the attached recall SRF even if you have **no** product inventory on hand, and then return the completed SRF 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 labels for Return Goods Authorization (RGA) and shipping after receipt of your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA 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 Stock Response Forms: Contact Inmar at: 855-874-6724 (dedicated phone line). Hours of Operation: M – F, 9.00 AM to 5.00 PM Eastern Time Recall Stock Response Forms - Contact Inmar at 855-874-6724 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 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com.
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

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

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.

Please fill out completely **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 #: _____

Shelf Pack NDC	Vial NDC	Lot #	Quantity of VIALS to Return
0703-1501-02	0703-1501-01	100022404	
0703-1501-02	0703-1501-01	100023333	

Additional Stock Response Forms included: ***Yes*** ☐ ***No*** ☐

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 promptly 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