Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 09/27/2018

Alprostadil Injection USP 500 micrograms/mL

1 mL Single Use Vial, 5 Vials/ Carton

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Lot #	Exp. Date	Strength	Size	Carton NDC	Vial NDC
31323147B	01/2019	500 micrograms/mL	1 mL Single Use Vial, 5 Vials/Carton	0703-1501-02	0703-1501-01

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Alprostadil Injection USP 500 micrograms/mL** distributed under the **Teva Pharmaceuticals USA, Inc. label.** This recall is being carried out to the **RETAIL /HOSPITAL/INSTITUION LEVEL** due to out-of-specification test results for impurities obtained during routine stability testing activities. The use of or exposure to the product is not expected to cause adverse health consequences.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Immediately examine your inventory for the specified lot of **Alprostadil Injection USP 500 micrograms/mL.**
- Our records indicate we shipped this product between September 26, 2017 and August 02, 2018.
- Immediately discontinue distribution of the specific lot being recalled.
- **Wholesalers/Distributors/Retailers: if you have further distributed the specific lot, please perform a SUB-RECALL to your Retail/Hospital/Institution accounts using this Recall Notification and Stock Response Form.**
- 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 and shipping label, if requested on your SRF. 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: 800-967-5952. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 800-967-5952 or acquire it from clsnetlink.com.
Customer Service-related Questions: Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week).
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM 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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Alprostadil Injection USP 500 micrograms/mL

1 mL Single Use Vial, 5 Vials/ Carton

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; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

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

Lot #	Exp. Date	Strength	Size	Quantity to Return # of Cartons of 5 Vials NDC# 0703-1501-02	Quantity to Return # of Single Vials NDC# 0703-1501-01
31323147B	01/2019	500 micrograms/mL	1 mL Single Use Vial, 5 Vials/Carton		

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: _____

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Please FAX this form to: 817-868-5362 or 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