Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 01/28/2020

DESMOPRESSIN ACETATE TABLETS, 0.1 mg and 0.2 mg

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

Lot #	Exp. Date	Strength	Bottle Size	NDC
1281203M	03/2020	0.1 mg	100 count	0591-2464-01
1290113M	04/2020	0.1 mg	100 count	0591-2464-01
1269726M	01/2020	0.2 mg	100 count	0591-2465-01
1283269M	03/2020	0.2 mg	100 count	0591-2465-01
1283270M	03/2020	0.2 mg	100 count	0591-2465-01
1292992M	04/2020	0.2 mg	100 count	0591-2465-01
1292993A	04/2020	0.2 mg	100 count	0591-2465-01

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the RETAIL LEVEL the above lots of **Desmopressin Acetate Tablets, 0.1 mg and 0.2 mg, 100 count** that was distributed under the Actavis Pharma Inc., label. This recall is being initiated due to the possibility of desiccant count discrepancy in the above lots. As per the product packaging specification, each product bottle is packaged with one (1) 2 Gram Sorb-it Canister desiccant. However, there is a possibility that the above lots may contain no desiccant. Based on the available information, the suspected risk of product bottle with no desiccant is reduced efficacy or lack of efficacy. However, patients treated with Desmopressin are subject to periodic clinical monitoring by their treating physician in order to evaluate the therapeutic response of the drug. Further, individual dose adjustment based on severity of symptoms and patient's response minimize the possible incident of reduced drug efficacy.

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

- Immediately examine your inventory for the specified lot of **Desmopressin Acetate Tablets, 0.1 mg and 0.2 mg, 100 count.**
- Our records indicate we shipped this product between March 13, 2018 and June 26, 2019.
- Immediately discontinue distribution of the specific lots being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lots, please perform a SUB-RECALL to your [retail/wholesale] 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.

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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.
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 3, then, option 3 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 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

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	Bottle Size	NDC	Quantity to Return (count partial as 1)
1281203M	03/2020	0.1 mg	100 count	0591-2464-01	
1290113M	04/2020	0.1 mg	100 count	0591-2464-01	
1269726M	01/2020	0.2 mg	100 count	0591-2465-01	
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1283270M	03/2020	0.2 mg	100 count	0591-2465-01	
1292992M	04/2020	0.2 mg	100 count	0591-2465-01	
1292993A	04/2020	0.2 mg	100 count	0591-2465-01	

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 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