Teva Pharmaceuticals USA, Inc.

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

Methylphenidate Hydrochloride Extended-Release Tablets USP (CII), 18 mg and 27 mg

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

Lot #	Exp. Date	Strength	Bottle Size	NDC
1332796A	11/2020	18 mg	100 count	62037-725-01
1332799A	11/2020	27 mg	100 count	62037-734-01

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the RETAIL LEVEL the above lots of **Methylphenidate Hydrochloride Extended-Release Tablets USP (CII), 18 mg and 27 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 Methylphenidate 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 lots of **Methylphenidate Hydrochloride Extended-Release Tablets USP (CII), 18 mg and 27 mg, 100 count.**
- Our records indicate we shipped this product between March 07, 2019 and September 16, 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, shipping label and **DEA 222 form***, 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.

NOTE: DO NOT return product until you have received the product return package which includes Return Goods Authorization label, Shipping Label and DEA 222 form. A copy of the completed DEA 222 form is required to process your return.

Teva Pharmaceuticals USA, Inc.

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

Methylphenidate Hydrochloride Extended-Release Tablets USP (CII), 18 mg and 27 mg

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.

Teva Pharmaceuticals USA, Inc.

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

Methylphenidate Hydrochloride Extended-Release Tablets USP (CII), 18 mg and 27 mg

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 (please print): _____ Telephone #: _____

Lot #	Exp. Date	NDC	Number of Full Bottles to Return*	Count of Tablets in Partial Bottles to Return*
1332796A	11/2020	62037-725-01		
1332799A	11/2020	62037-734-01		

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: _____

** Note: Please print the correct count of tablets in partial bottle and number of full bottle to return in order to generate the DEA 222 form.*

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