Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – WHOLESALE LEVEL - INITIATED 6/17/16

Ondansetron Injection USP 40 mg/20mL (2 mg/mL)

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

All Lots Within Expiry

Ondansetron Injection USP 40 mg/20mL (2 mg/mL)
NDC# 0703-7226-01 20 mL - Multi-dose Vial

Ondansetron Injection USP 40 mg/20mL (2 mg/mL)
NDC# 0703-7226-03 - 10 Multi-dose Vials in One Carton

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling all lots within expiry of **Ondansetron Injection USP 40 mg/20mL (2 mg/mL)** distributed under the **Teva Pharmaceuticals label.** This recall is being carried out to the wholesale level in order to align with FDA Import Alert (IA) 66-40, which was issued because the methods and controls used in the manufacture and control of the product do not appear to conform to current good manufacturing practice (CGMP). Teva is not aware of any safety signals for this product and this product does not present a safety risk to patients.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Ondansetron Injection USP 40 mg/20mL (2 mg/mL)**
- Our records indicate we shipped this product between February 25, 2015 and July 9, 2015.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your WHOLESALE level accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: rxrecalls@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and 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 product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For medical-related questions please contact Medical Information at 888-838-2872, option 3, then, option 4 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-4:30PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time) or acquire it from clsnetlink.com.

Sincerely,

James S. Young
Director, Quality Systems & 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; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

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

Lot #	Exp. Date	Vial Size	Quantity to Return # of single Multi-dose Vials NDC# 0703-7226-01
2930614	6/2016	20 mL	
2940614	6/2016	20 mL	
			Quantity to Return # of cartons of 10 Multi-dose Vials NDC# 0703-7226-03 (count partials as 1)
2950614	6/2016	20 mL	

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: _____

Inquiries regarding this Recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time)

Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Medical-related questions - contact Medical Information 888-838-2872, option 3, then, option 4

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-4:30PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3

(Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Please fax this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com

Inmar/MedTurn Use Only:

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