

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL - INITIATED 4/23/14

QVAR® (beclomethasone dipropionate HFA), 80mcg Inhalation Aerosol

MANUFACTURED BY:
3M Drug Delivery Systems
Northridge, CA 91324

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

Lot #	Exp. Date	NDC #	Strength	Size
130140	11/2014	59310-204-85	80 mcg	4.2g / 50 metered inhalations
130143	3/2015	59310-204-80	80 mcg	8.7g / 120 metered inhalations
130144	3/2015	59310-204-80	80 mcg	8.7g / 120 metered inhalations

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **QVAR® (beclomethasone dipropionate HFA), 80mcg Inhalation Aerosol** distributed under the **Teva** label. This recall is being carried out to the **RETAIL LEVEL** due to a defective valve. The probability of serious health consequences is likely remote.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **QVAR® (beclomethasone dipropionate HFA), 80mcg Inhalation Aerosol**.
- Our records indicate we shipped this product between June 20, 2013 and September 24, 2013.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your RETAIL 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: recallnotice@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 recalled 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. For medical-related questions please contact Medical Affairs at 888-4-TEVA-RX (888-483-8279), option 2. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,



David L. Roberts
Director, Quality Systems
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 4/23/14

STOCK RESPONSE FORM

QVAR[®] (beclomethasone dipropionate HFA), 80mcg Inhalation Aerosol

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	NDC #	Strength	Quantity to Return
130140	11/2014	59310-204-85	80 mcg	
130143	3/2015	59310-204-80	80 mcg	
130144	3/2015	59310-204-80	80 mcg	

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. Please **do not resubmit** response form.

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

Medical related questions - contact Medical Affairs at 888-4-TEVA-RX (888-483-8279), option 2.

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

Inmar/MedTurn Use Only: _____

Scan	Labels	Store	Kit	D.B
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