

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL

Licensed Health Care Practitioner LEVEL – INITIATED 2/24/16

Children's Qnasl® 40 mcg (beclomethasone dipropionate) Nasal Aerosol

RECALLED BY:

**Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044**

Lot #	Exp. Date	Strength	Nasal Aerosol Size	NDC
150096	3/2017	40 mcg	60 metered sprays/4.9 g	59310-206-06

Dear J. Knipper and Company, Inc.:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above combination lot and NDC number of **Children's Qnasl® 40 mcg (beclomethasone dipropionate) Nasal Aerosol** distributed under the **Teva Respiratory, LLC** label. This recall is being carried out to the Licensed Health Care Practitioner LEVEL due to a shipping error which resulted in the distribution of commercial product to the Licensed Health Care Practitioners with labels and cartons not identified as samples. Please note that this recall does NOT include the commercial product of the same lot number and NDC code that was correctly distributed to the commercial distribution chain. It only includes the commercial product incorrectly distributed as physician samples. The use of or exposure to the product is not expected to have any adverse health consequence.

Please perform the following activities:

Trade Accounts: No action required.

Physician Sample Distribution:

- Examine your inventory immediately for the specified combination lot and NDC number of **Children's Qnasl® 40 mcg (beclomethasone dipropionate) Nasal Aerosol**.
- Our records indicate we provided this product on August 26, 2015.
- Immediately discontinue distribution of the specific combination lot and NDC number being recalled.
- **Please perform a SUB-RECALL to the Licensed Health Care Practitioner accounts using this Recall Notification and appropriate 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 Information at 888-483-8279, option 2. For product complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 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	Strength	Nasal Aerosol Size	NDC	Quantity to Return (count partial as 1)
150096	3/2017	40 mcg	60 metered sprays/4.9 g	59310-206-06	

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 Information at 888-483-8279, option 2.

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

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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