



ADDENDUM -- SEPTEMBER 18, 2018
URGENT VOLUNTARY PRODUCT RECALL

**All lots of Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.),
Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.)**

September 11, 2018

Dear Valued Valeant Customer,

Valeant Pharmaceuticals is conducting a voluntary recall **at the retail level** of all lots of Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) within expiration. A complete list of the products impacted by this voluntary recall is attached (see page 4).

Valeant is voluntarily recalling these products in response to a recent notification from Product Quest, the manufacturer of Cortaid®. The notification stated that Product Quest is conducting a voluntary recall of all of its nasal products and baby oral gels due to the possibility of microbial contamination identified as *Pseudomonas Aeruginosa* (a Gram-negative bacterium). Product Quest became aware of these findings following an internal quality review at their facility.

Our customers and their patients are our top priority. Although the likelihood of any major infection to a healthy consumer because of microbiological contamination issues due to *Pseudomonas Aeruginosa* is low, Valeant decided to take the necessary steps to voluntarily recall these Cortaid® products out of an abundance of caution since they are manufactured in the same facility. It is important to note that individuals who have a weak immune system may be at higher risk for severe infections due to *Pseudomonas Aeruginosa* contamination.

VOLUNTARY RECALLED PRODUCT DETAILS



Product:

- Cortaid® Maximum Strength Cream (1 oz.)
- Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.)
- Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.)

Lot Numbers: All Lots

UPC Codes: 301875519155, 301875521011 & 301875518028

QUARANTINE PRODUCT AND RETURN TO VALEANT

According to our records, your facility may have a supply of Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) within expiration. We are asking for your immediate assistance to quarantine all of the product in your inventory and take the following steps to return the product to Valeant:



1. Please review your inventory, including floor displays, for all Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) and remove the product from your inventory.
2. Please contact Stericycle, the firm conducting this product recall on behalf of Valeant at 1-888-480-2881, to arrange the return of the product identified from your inventory.
 - a. **Wholesalers/Distributors**
 - i. If arranging pickup of product, freight will be prepaid by Stericycle. Alternately, you may arrange shipment of the product directly to Stericycle at the following address: Stericycle, Inc., Attn: Event 6684, 2670 Executive Drive, Suite A, Indianapolis, IN 46241.
 - ii. **Wholesalers/Distributors are asked to send the retailer list for the product via Microsoft Excel file to Valeant6684@stericycle.com within 5 business days. Valeant will then have Stericycle notify the retailers that were included within the Microsoft Excel list.**
 - b. **Retailers**
 - i. **Please contact Stericycle, the firm conducting this product recall on behalf of Valeant, at 1-888-480-2881, to arrange the return of the product identified from your inventory.**
 - ii. **If you have a process to return product for reclamation, your stores may return the product to your reclamation center for processing. All product must be forwarded to Stericycle, the firm managing this voluntary product recall on behalf of Valeant, for proper accounting and reporting purposes.**
3. Finally, please complete the enclosed **Product Recall Acknowledgement Form** and return it to Valeant via email at Valeant6684@stericycle.com or fax at 1-888-240-2809 within 5 days. **It is important to return the Recall Acknowledgement Form even if you do not have any Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) in your inventory.**

If you have questions about this voluntary recall process or would like additional information, please contact Stericycle, Inc., the firm managing this voluntary product recall on behalf of Valeant, at 1-888-480-2881.

We greatly appreciate your understanding and prompt assistance, and apologize for any inconvenience this may cause.

Sincerely,

A handwritten signature in black ink that reads "Sandra Minera".

Sandra Minera
Senior Director, External Manufacturing Quality Assurance

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URGENT VOLUNTARY PRODUCT RECALL ACKNOWLEDGEMENT FORM

This is to acknowledge receipt of the Valeant Voluntary OTC Product Recall notification for Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) dated Sept. 11, 2018.

Product Details:

All lots of Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.)

Please review and acknowledge (X) the following statement below:

- We have reviewed the attached Valeant Voluntary OTC Product Recall notification and acknowledge the alert.

Please review and acknowledge (X) one of the statements below that applies to your facility:

- We do not have any of these impacted Cortaid® products in our inventory.
- We do have these impacted Cortaid® products in our inventory. If checked, please fill out chart below.

Please insert the total number of Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) identified in your facility:

UPC Number	Lot Number	Quantity Received	Quantity Returned

I hereby certify that I have quarantined the above listed product to prevent use and will return any of the impacted Cortaid® products identified in my inventory to Stericycle.

Name (Print)	Date
_____	_____
Signature	Telephone Number
_____	_____
Location	Account Number
_____	_____

Please complete, sign and return this form to:

Phone: 1-888-480-2881 **Email:** Valeant6684@stericycle.com **Fax:** 1-888-240-2809

Confidentiality Agreement: The information contained in this facsimile message is privileged and confidential information intended for the use of the addressee listed above. If you are neither the intended recipient nor the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of the information is strictly prohibited. If you have received this in error, please immediately notify us by telephone to arrange for the return of the original document to us. © 2018 Valeant Pharmaceuticals North America LLC. CTD.0014.USA.18

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URGENT VOLUNTARY PRODUCT RECALL

Cortaid® 12-Hour Advanced Anti-Itch Cream (1.5 oz.), Cortaid® Maximum Strength Cream (1 oz.) and Cortaid® Intensive Therapy Cooling Spray (2 fl. oz.) Products Impacted

CORTAID® 12-HOUR ADVANCED ANTI-ITCH CREAM, 1.5 OZ.	
UPC Code: 301875519155	
LOT NUMBER:	EXPIRATION DATE:
172185F	06/19

CORTAID® MAXIMUM STRENGTH CREAM, 1 OZ.	
UPC Code: 301875521011	
LOT NUMBER:	EXPIRATION DATE:
170843B	02/19
171484D	04/19
171791E	05/19
171848E	05/19
172359J	09/19
172360J	09/19
173184J	09/19
173512P	12/19
180180B	02/20
181098C	03/20

CORTAID® INTENSIVE THERAPY COOLING SPRAY, 2 FL. OZ.	
UPC Code: 301875518028	
LOT NUMBER:	EXPIRATION DATE:
171205E	05/2019
171951E	05/2019
173365K	10/2019