



URGENT VOLUNTARY PRODUCT RECALL
All lots of Ocean® Saline Nasal Spray

September 20, 2018

Dear Valued Valeant Customer,

Product Quest, the manufacturer of Ocean® Saline Nasal Spray, has requested that Valeant voluntarily recall at the retail level all lots of our Ocean® Saline Nasal Spray products. These products include all Ocean® Saline Nasal Spray products within expiration (1.5 fl. oz., 3.5 fl. oz. and a buddy pack consisting of a 0.76 fl. oz. bottle and a 1.5 fl. oz. bottle). Ocean® Nasal Spray is used to treat dryness inside the nose (nasal passages) due to colds, allergies, dry eye, pollution, smoke, air travel and use of decongestant steroidal sprays. A complete list of products impacted by this voluntary recall is attached (see pages 4-13).

Product Quest has requested that we voluntarily recall these products due to possible out-of-specification results related to microbial contamination - *Pseudomonas aeruginosa* (a gram-negative bacterium). Product Quest became aware of these findings following an internal quality review at their facility.

Although there has been no known reported microbial contamination associated with Ocean® Saline Nasal Spray, we are following Product Quest's request to voluntarily recall this product out of an abundance of caution.

Please note that if certain patient populations, including those with cystic fibrosis or those who have compromised immune systems, frequently use a nasal spray containing gram-negative bacterium they could develop a life threatening infection.

VOLUNTARY RECALLED PRODUCT DETAILS



Product: Ocean® Saline Nasal Spray (1.5 fl. oz., 3.5 fl. oz. and a buddy pack consisting of a 0.76 fl. oz. bottle and a 1.5 fl. oz. bottle)

Lot Numbers: All Lots

UPC Codes: 301875260026
301875260019
301875260033

QUARANTINE PRODUCT AND RETURN TO VALEANT

According to our records, your facility may have a supply of Ocean® Saline Nasal Spray. We are asking for your immediate assistance to quarantine all Ocean® Saline Nasal Spray in your inventory and take the following steps to return the product to Valeant:

1. Please review your inventory, including floor displays, for Ocean® Saline Nasal Spray impacted by this voluntary recall and remove the product from your inventory.

2. Please contact Stericycle, the firm managing this voluntary product recall on behalf of Valeant, to arrange the return of the impacted Ocean® Saline Nasal Spray product 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 8985, 2670 Executive Dr., Suite A, Indianapolis, IN 46241.
 - ii. Wholesalers/Distributors are asked to send the retailer list for the product via Microsoft Excel file to Valeant8985@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 1-888-667-1502, 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 Valeant8985@Stericycle.com or fax at 1-877-546-2984 within 5 days. It is important to return the Recall Acknowledgement Form even if you do not have any Ocean® Nasal Spray 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 1-888-667-1502.

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

Sincerely,



Sandra Minera
Senior Director of External Manufacturing Quality Assurance



URGENT VOLUNTARY PRODUCT RECALL ACKNOWLEDGEMENT FORM

This is to acknowledge receipt of the Valeant Voluntary Product Recall notification for Ocean® Saline Nasal Spray dated Sept. 20, 2018.

Product Details:

All lots of Ocean® Saline Nasal Spray (1.5 fl. oz., 3.5 fl. oz. and a buddy pack consisting of a 0.76 fl. oz. bottle and a 1.5 fl. oz. bottle)

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

- We have reviewed the attached Valeant Voluntary 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 Ocean® Saline Nasal Spray from the impacted lots in our inventory.
- We do have Ocean® Saline Nasal Spray from the impacted lots in our inventory. If checked, please fill out chart below.

Please insert the total number of impacted Ocean® Saline Nasal Spray identified in your facility:

Lot No.	No. Received	No. Returned

I hereby certify that I have quarantined the above listed product to prevent use and will return any impacted Ocean® Saline Nasal Spray product identified in my inventory to Valeant.

Name (Print)

Date

Signature

Telephone Number

Location

Account Number

Please complete, sign and return this form to:

Fax: 1-877-546-2984

Email: Valeant8985@stericycle.com

Phone: 1-888-667-1502

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 DCN 0014 USA.18

URGENT VOLUNTARY PRODUCT RECALL
List of Ocean® Saline Nasal Spray Products Impacted

OCEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
153248J	09/18
153376J	09/18
153377J	09/18
153378J	09/18
153754M	11/18
153755M	11/18
153756M	11/18
153757M	11/18
153856M	11/18
153857M	11/18
153858M	11/18
153859M	11/18
153860M	11/18
153933M	11/18
153934M	11/18
154295P	12/18
154296P	12/18
154297P	12/18
154298P	12/18
154299P	12/18
154504P	12/18
160057A	01/19
160058A	01/19
160111A	01/19
160112A	01/19
160113A	01/19
160114A	01/19
160115A	01/19
160918C	03/19
160919C	03/19
160920C	03/19
161047C	03/19
161048C	03/19

OCEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875280019	
LOT NUMBER:	EXPIRATION DATE:
161049C	03/19
161050C	03/19
161051C	03/19
161052C	03/19
161053C	03/19
161054C	03/19
161115C	03/19
161116C	03/19
161117C	03/19
161118C	03/19
161119C	03/19
161120C	03/19
161173C	03/19
161439D	04/19
161440D	04/19
161481D	04/19
161482D	04/19
161483D	04/19
161484E	05/19
161592D	04/19
161595E	05/19
161596E	05/19
161597E	05/19
161598E	05/19
161647E	05/19
161648E	05/19
161649E	05/19
161651E	05/19
161652E	05/19
161653E	05/19
161654E	05/19
161656E	05/19
161720E	05/19
161721E	05/19

OCEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
161722E	05/19
161723E	05/19
161724E	05/19
161725E	05/19
161726E	05/19
161727E	05/19
162115F	06/19
162116F	06/19
162117F	06/19
162145F	06/19
162146F	06/19
162147F	06/19
162174G	07/19
162449G	07/19
162452H	08/19
162453H	08/19
162454H	08/19
162455H	08/19
162456H	08/19
162458H	08/19
162459H	08/19
162709H	08/19
162710H	08/19
162770H	08/19
162782H	08/19
162788H	08/19
162836H	08/19
162838H	08/19
162859H	08/19
162889H	08/19
162995H	08/19
162996H	08/19

OCEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
162997H	08/19
162998J	09/19
162999J	09/19
163000J	09/19
163001J	09/19
163002J	09/19
163003J	09/19
163004J	09/19
163005J	09/19
163006J	09/19
163051J	09/19
163354K	10/19
163355K	10/19
163357K	10/19
163358K	10/19
163359K	10/19
163360K	10/19
163361K	10/19
163436K	10/19
163437K	10/19
163438K	10/19
163487K	10/19
163557K	10/19
163558K	10/19
163559K	10/19
163560M	11/19
163561M	11/19
163562M	11/19
163563M	11/19
163623M	11/19
170630B	02/19
170631B	02/19
170632B	02/19

OGEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
170633B	02/19
170634B	02/19
170635B	02/19
170636B	02/19
170637B	02/19
170782C	03/19
170783C	03/19
170784C	03/19
170785C	03/19
170786C	03/19
170952C	03/19
171051D	04/19
171052D	04/19
171053D	04/19
171054D	04/19
171055D	04/19
171229D	04/19
171230D	04/19
171231D	04/19
171232D	04/19
171233D	04/19
171577E	05/19
171578E	05/19
171579E	05/19
171580E	05/19
171821E	05/19
171822E	05/19
171823E	05/19
171824E	05/19
171825E	05/19
171875F	06/19
172083F	06/19
172085F	06/19

OGEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
URC Code: 301875280019	
LOT NUMBER:	EXPIRATION DATE:
172086F	06/19
172087F	06/19
172088F	06/19
172089F	06/19
172090F	06/19
172091F	06/19
172092F	06/19
172150F	06/19
172151F	06/19
172152F	06/19
172153F	06/19
172154F	06/19
172155F	06/19
172156F	06/19
172157F	06/19
172158F	06/19
172159F	06/19
172160F	06/19
172252F	06/19
172253F	06/19
172254F	06/19
172255G	07/19
172256F	06/19
172257F	06/19
172258F	06/19
172259F	06/19
172380F	06/19
172477G	07/19
172478G	07/19
172479G	07/19
172480G	07/19
172484G	07/19
172485G	07/19

OCEAN® SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
172599G	07/19
172600G	07/19
172602G	07/19
172736G	07/19
172737G	07/19
172739H	08/19
172951H	08/19
172953H	08/19
172954H	08/19
172955H	08/19
172956H	08/19
172957H	08/19
173120J	09/19
173121J	09/19
173122J	09/19
173123J	09/19
173124J	09/19
173125J	09/19
173126J	09/19
173221J	09/19
173227K	10/19
173228K	10/19
173340K	10/19
173341K	10/19
173342K	10/19
173343K	10/19
173344K	10/19
173465K	10/19
173466K	10/19
173467K	10/19
173468K	10/19
173469K	10/19
173658P	12/19

OGEAN[®] SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPG Code: 301875280019	
LOT NUMBER:	EXPIRATION DATE:
173659P	12/19
173660P	12/19
173661P	02/20
173662P	02/20
173663P	12/19
173664P	12/19
173665P	12/19
173666P	12/19
173667P	12/19
173668P	12/19
173786P	12/19
173787P	12/19
173788P	02/20
173790P	02/20
173791P	12/19
180036A	02/20
180232A	01/20
180233A	01/20
180234A	01/20
180235A	01/20
180236A	01/20
180237A	01/20
180258A	01/20
180259A	01/20
180260A	01/20
180261A	01/20
180262A	01/20
180365B	03/20
180522B	07/20
180581B	02/20
180582B	02/20
180583B	02/20
180584B	02/20
180585B	02/20
180586B	02/20
180587B	02/20
180588B	02/20
180589B	02/20

OCEAN[®] SALINE NASAL SPRAY, 3.5 FL. OZ.	
UPC Code: 301875260019	
LOT NUMBER:	EXPIRATION DATE:
180590B	02/20
181353D	04/20
181354D	04/20
181356D	04/20
181357D	04/20
181358D	04/20
181626E	05/20
181682E	05/20
181683E	05/20
181711E	07/18
181818F	07/20
181819F	07/20
181826F	07/20
181839F	07/18
OCEAN SALINE BUDDY PACK (consists of 1.5 FL. OZ. and 0.76 FL. OZ.)	
UPC Code: 301875260026	
LOT NUMBER:	EXPIRATION DATE:
153440K	10/18
153441K	10/18
153753M	11/18
153754M	11/18
154299P	12/18
154300P	12/18
161413D	04/19
161435D	04/19
162151G	07/19
162173G	07/19
162174G	07/19
163441K	10/19
163487K	10/19
163557K	10/19
171049C	03/19
171050C	03/19
173034H	08/19
173035H	08/19
180174A	02/20
180175A	02/20
180176A	01/20
180177A	02/20

OGEAN SALINE NASAL SPRAY, 1.5 FL. OZ.	
UPC Code: 301875280083	
LOT NUMBER:	EXPIRATION DATE:
153440K	10/18
153441K	10/18
153753M	11/18
153754M	11/18
154299P	12/18
154300P	12/18
161413D	04/19
161435D	04/19
162151G	07/19
162173G	07/19
162174G	07/19
163441K	10/19
163487K	10/19
163557K	10/19
171049C	03/19
171050C	03/19
173034H	08/19
173035H	08/19
180174A	02/20
180175A	02/20
180176A	01/20
180177A	02/20