

July 9, 2019

COM-2019-030

Recall: Voluntary Recall of Multiple Ophthalmic Products - Altaire Pharmaceuticals

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on July 3, 2019, the US Food and Drug Administration (FDA) issued a statement notifying that Altaire Pharmaceuticals, Inc. is voluntarily recalling multiple ophthalmic products and lots. The recall was made as a precautionary measure due to the potential for non-sterility. The affected lots by the recall are detailed below:

Affected Ophthalmic Products:

1. Product Description: Neomycin and Polymixin B and Bacitracin Zinc Ophthalmic Ointment NDC Number: 0574-4250-35 Package Size: 3.5 gm		
Lot Number	Expiration Date	Manufacturer Initial Ship Date
SAC	1/20	1/29/2018
SLK	12/20	1/30/2019

2. Product Description: NEO-POLY DEX (Neomycin and Polymixin B and Dexamethasone) Ophthalmic Ointment NDC Number: 0574-4160-35 Package Size: 3.5 gm		
Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGC	7/19	8/7/2017
RHB	8/19	8/30/2017
RHC	8/19	8/30/2017
RID	9/19	10/2/2017
RIC	9/19	10/2/2017
RIG	9/19	10/23/17
RKH	11/19	12/8/2017
RKI	11/19	12/8/2017
RKJ	11/19	12/15/2017
RKK	11/19	12/15/2017
RKL	11/19	12/20/2017
RLM	12/19	1/29/2018
SAI	1/20	2/26/2018
SBG	2/20	3/12/2018
SBH	2/20	3/22/2018

2. (Continuation) Product Description: NEO-POLY DEX (Neomycin and Polymixin B and Dexamethasone) Ophthalmic Ointment NDC Number: 0574-4160-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SCF	3/20	4/23/2018
SEA	5/20	5/23/2018
SFA	6/20	6/20/2018
SFB	6/20	8/14/2018
SHA	8/20	8/30/2018
SIB	9/20	10/2/2018
SJC	10/20	11/9/2018
TAB	1/21	1/30/2019
TAF	1/21	2/18/2019
TBP	2/21	3/18/2019
TBQ	2/21	3/18/2019
TCV	3/21	5/1/2019
TCW	3/21	5/1/2019

3. Product Description: NEO-POLYCIN HC (Neomycin and Polymixin B and Bacitracin Zinc and Hydrocortisone Acetate) Ophthalmic Ointment NDC Number: 0574-4144-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SEE	5/20	5/31/2018
SEG	5/20	7/13/2018
SIE	9/20	10/17/2018
SKD	11/20	12/27/2018

4. Product Description: POLYCIN (Polymixin B and Bacitracin Zinc) Ophthalmic Ointment NDC Number: 0574-4021-35 Package Size: 3.5 gm

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGD	7/19	8/17/2017
RHL	8/19	9/28/2017
RHB	9/19	10/23/2017
RJF	10/19	11/8/2017
RJG	10/19	11/7/2017
SAJ	1/20	2/12/2018
SAK	1/20	2/19/2018
SAL	1/20	2/19/2018
SAM	1/20	2/22/2018
SBK	2/20	3/22/2018
SEH	5/20	6/20/2018
TCD	3/21	5/1/2019

5. Product Description: Bacitracin Ophthalmic Ointment NDC Number: 0574-4022-35 Package Size:3.5 gm		
Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGA	7/19	7/31/2017
RGE	7/19	8/11/2017
RGG	7/19	8/11/2017
RGH	7/19	8/17/2017
RHM	8/19	9/14/2017
RJB	10/19	10/23/2017
RJA	10/19	10/23/2017
SCA	3/20	3/22/2018
SIC	9/20	10/9/2018
TAP	1/21	2/26/2019
TDE	4/21	5/30/2019

6. Product Description: Sulfacetamide Sodium Ophthalmic Ointment NDC Number: 0574-4190-35 Package Size: 3.5 gm		
Lot Number	Expiration Date	Manufacturer Initial Ship Date
RID	10/19	10/30/2017
SHG	8/20	9/13/2018

7. Product Description: Puralube Ophthalmic Ointment (Please note: Puralube is an OTC product)				
Lot Number	Expiration Date	NDC Number	Package Size	Manufacturer Initial Ship Date
RJH	10/19	0574-4025-35	3.5 gm	11/13/2017
SCC	3/21			3/29/2018
SGA	7/21			7/31/2018
SGH	7/21			8/30/2018
SHH	8/21			9/13/2018
SLL	12/21			1/30/2019
TAC	1/22			2/18/2019
RKM	11/19	0574-4025-20	1 gm	12/8/2017
SGA	7/20			7/31/2018
SIF	9/20			10/17/2018
SKE	11/20			

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.

2. Contact all members that in the previous 90 days received the recalled medication and advised them to contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the drug product.
3. Any question regarding this recall should be directed to Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing otcdruggist@aol.com Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET.

For additional information visit:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/altaire-pharmaceuticals-inc-issues-voluntary-recall-multiple-ophthalmic-products>

Clinical Department