

COMPANY ANNOUNCEMENT

Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 02, 2019

FDA Publish Date:

July 03, 2019

Product Type:

Drugs

Generic Drugs

Reason for Announcement:

Potential for nonsterility

Company Name:

Altaire Pharmaceuticals, Inc.

Brand Name:

Perrigo

Product Description:

Ophthalmic ointments

Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the prescription drug products and lots, within expiry, distributed during the time period as indicated in the tables below. As a precautionary measure, Altaire is initiating the recall due to management

concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. This recall is being carried out to the retail level and is only for the specific lots listed. No other lots are being recalled.

Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death. To date, Altaire has received no reports of adverse events, nor has Altaire obtained any out of specifications results including sterility testing, for the products.

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

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

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SBG	2/20	3/12/2018
SBH	2/20	3/22/2018
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

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

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

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

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

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
Lot Number	Expiration Date	NDC Number	Package Size	Manufacturer Initial Ship Date
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			12/27/2018

The products are manufactured and labeled exclusively for Perrigo Company PLC. Altaire ships the products only to Perrigo Company PLC. The products are distributed by Perrigo Company PLC.

Altaire has notified Perrigo by e-mail on July 2, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots. Altaire has also requested that Perrigo perform a subrecall, and that Perrigo notify its customers.

Customers with questions regarding this recall can contact Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing otcdruggist@aol.com (<mailto:otcdruggist@aol.com>) Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online \(/node/360543\)](/node/360543)
- Regular Mail or Fax: [Download form \(/node/360547\)](/node/360547) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Altaire takes its mission of customer safety and providing quality products very seriously. The company is committed to, and diligently working to, ensure the sufficiency of Quality Assurance controls over critical systems in its manufacturing facility.

Company Contact Information

Consumers:

Altaire Pharmaceuticals Inc

☎ 1-800-258-2471

✉ otcdruggist@aol.com (<mailto:otcdruggist@aol.com>)

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