

**COMPANY ANNOUNCEMENT**

# Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Manufactured and Distributed as Altaire Labeled 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 15, 2019

**FDA Publish Date:**

July 15, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

Due to lack of sterility assurance

**Company Name:**

Altaire Pharmaceuticals Inc.

**Brand Name:**

Altaire Pharmaceuticals, Inc.

**Product Description:**

OTC and Rx Ophthalmic Products

## Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the over the counter (OTC) and prescription (Rx) drug products and lots, within expiry, it has manufactured and distributed under the Altaire label and trade dress during the time period as indicated below. As a precautionary measure, Altaire is voluntarily initiating this recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical

systems in the manufacturing facility. The FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections or death.

This recall is being carried out to the RETAIL LEVEL and IS ONLY FOR THE SPECIFIC LOTS LISTED BELOW. No other lots are being recalled. A Retail Level recall is limited to product lots currently in inventory on hand at any distributor to which Altaire Pharmaceuticals, Inc. has sold these products.

Altaire further advises as follows:

TO DATE, ALTAIRE HAS NOT RECEIVED ANY REPORTS OF ADVERSE EVENTS FOR THE PRODUCTS.

TO DATE, ALTAIRE HAS NOT OBTAINED ANY OUT OF SPECIFICATION RESULTS, INCLUDING IN-HOUSE AND THIRD-PARTY STERILITY TESTING, FOR THESE PRODUCTS.

Product Description: ActivEyes Nighttime Lub Eye Ointment Preservative Free NDC#: 59390-190-50 Product Size: 3.5 g

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SKG	11/21	12/28/2018
TAQ	01/22	04/23/2019

Product Description: Altaire Altacaine Solution NDC#: 59390-181-13 Product Size: 15 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17205	07/19	08/31/2017
17206	07/19	09/13/2017
17271	09/19	11/08/2017
18003	01/20	03/06/2018
18097	04/20	05/11/2018
18166	07/20	07/26/2018
18227	09/20	10/05/2018
18246	10/20	11/16/2018

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18317	12/20	12/18/2018
19080	03/21	04/22/2019
19106	04/21	05/21/2019

Product Description: ActivEyes Altachlore Ointment NDC#: 59390-184-50 Product Size: 3.5 gram

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SAP	1/20	3/16/2018
SFI	6/20	8/16/2018
SLA	12/20	1/4/2019
TBM	2/21	3/28/2019

Product Description: ActivEyes Altachlore Solution NDC#: 59390-183-13 Product Size: 15 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18008	1/20	8/13/2018
19050	2/22	3/18/2019
19105	4/22	6/14/2019

Product Description: ActivEyes Altalube Ointment NDC#: 59390-198-50 Product Size: 3.5 gram

Lo Number	Expiration Date	Manufacturer Initial Ship Date
RJH	10/20	1/10/2018
RLL	12/20	8/22/2018
SGH	07/21	8/23/2018
SIF	09/21	10/16/2018
SKC	11/21	12/12/2018
TCG	03/22	4/22/2019

Product Description: Altaire Ciprofloxacin HCl Ophthalmic Solution 0.3% NDC#: 59390-217-02

Product Size: 2.5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18164	7/20	10/2/2018

Product Description: Altaire Ciprofloxacin HCl Ophthalmic Solution 0.3% NDC#: 59390-217-05

Product Size: 5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18164	7/20	8/15/2018

Product Description: Altaire Ciprofloxacin HCl Ophthalmic Solution 0.3% NDC#: 59390-217-10

Product Size: 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18164	7/20	8/15/2018

Product Description: Altaire Diclofenac Sodium Solution 1% NDC#: 59390-149-02 Product Size:

2.5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17247	8/19	11/17/2017

Product Description: Altaire Diclofenac Sodium Solution 1% NDC#: 59390-149-05 Product Size:

5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17225	8/19	10/16/2017
17247	8/19	12/26/2017
18038	2/20	3/22/2018
18162	6/20	7/18/2018
19014	1/21	2/14/2019

Product Description: Altaire Fluorescein Sodium with Proparacaine HCl Ophthalmic Solution

NDC#: 59390-205-05 Product Size: 5 mL

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17099	4/20	6/1/2017
17254	8/20	9/14/2017
17255	8/20	9/15/2017
17361	12/20	12/26/2017
17362	12/20	4/4/2018
18088	4/21	4/30/2018
18089	4/21	5/1/2018
18138	6/21	6/25/2018
18146	6/21	6/29/2018
18156	6/21	8/6/2018
18212	8/21	10/2/2018
18276	11/21	12/26/2018
19082	3/22	5/1/2019
19098	4/22	5/21/2019
16282	10/19	11/11/2016
16283	10/19	01/24/2016

Product Description: Altaire Eye Wash NDC#: 59390-175-13 Product Size: 15 mL

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17241	8/20	8/24/2017
17322	10/20	12/21/2017
18169	7/20	7/30/2018
19052	2/22	3/29/2019

Product Description: Altaire Eye Wash NDC#: 59390-175-18 Product Size: 1 Fl. Oz.

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
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Lot Number	Expiration Date	Manufacturer Initial Ship Date
17200	7/19	7/28/2017
17322	10/20	11/27/2017
18026	1/21	3/5/2018
18100	4/21	6/18/2018
18236	9/21	11/1/2018
19052	2/22	3/22/2019

Product Description: Altaire Eye Wash NDC#: 59390-175-35 Product Size: 4 Fl. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17087	3/20	4/18/2017
17088	3/20	4/28/2017
17109	4/20	5/15/2017
17110	4/20	6/12/2017
17306	10/20	11/1/2017
17307	10/20	11/3/2017
17318	10/20	12/21/2017
17323	10/20	1/30/2018
18014	1/21	4/10/2018
18045	2/21	4/16/2018
18059	3/21	5/29/2018
18063	3/21	4/18/2018
18117	5/21	6/14/2018
18134	5/21	8/24/2018
18228	9/21	11/2/2018
18261	10/21	1/8/2019
19119	4/22	6/3/2019

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
16207	8/19	09/15/2016
16233	8/19	09/29/2016
16250	9/19	10/28/2016
16268	10/19	11/04/2016
16301	11/19	12/09/2016

Product Description: Altaire Goniotaire NDC#: 59390-182-13 Product Size: 15 mL

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17112	4/20	6/1/2017
17303	10/20	12/4/2017
18032	2/21	2/22/2018
18072	3/21	4/17/2018
18193	8/20	8/16/2018
18235	9/21	10/15/2018
18285	11/21	12/17/2018
19004	1/22	1/24/2019
19102	4/22	5/15/2019
16260	9/19	10/25/2016

Product Description: Altaire Homatropaire NDC#: 59390-192-05 Product Size: 5 mL

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17041	2/20	6/01/2017
17186	6/20	11/10/2017
18068	3/21	8/17/2018

Product Description: NanoTears HA PF Multi Dose Lubricant Gel Drops NDC#: 59390-208-10  
Product Size: 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19122	4/21	5/31/2019

Product Description: Nano Tears MO Clear Emollient Mineral Oil Lipids NDC#: 59390-145-10  
Product Size: 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18052	2/20	5/16/2018

Product Description: Nano Tears MXP Forte Clear Emollient Lubricant Gel Drops NDC#: 59390-144-10 Product Size: 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17367	12/19	2/16/2018
18102	4/20	8/9/2018
18174	7/20	9/11/2018

Product Description: Nano Tears MXP Forte Clear Emollient Lubricant Gel Drops Twin Pack NDC#: 59390-144-51 Product Size: 2 x 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17367	12/19	5/16/2018
18174	7/20	8/24/2018

Product Description: Nano Tears TF Clear Emollient Tear Film Replenishment Essential Lipids Preservative Free Multi-Dose NDC#: 59390-141-52 Product Size: 7.5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19123	4/21	6/07/2019

Product Description: Nano Tears MXP Forte Clear Emollient Lubricant Gel Drops Preservative Free NDC#: 59390-147-56 Product Size: 0.6 mL x 32 ct.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGK	7/19	11/6/2017



Lot Number	Expiration Date	Manufacturer Initial Ship Date
SDA	4/20	4/27/2018
SFH	6/20	8/16/2018
TAN	1/21	5/23/2019

Product Description: Nano Tears TF Clear Emollient Lubricant Gel Drops Preservative Free  
NDC#: 59390-141-56 Product Size: 0.6 mL x 32 ct.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGI	7/19	1/5/2018
SDB	4/20	5/16/2018
TAA	1/21	3/13/2019

Product Description: Nano Tears TF Clear Emollient Lubricant Gel Drops Twin Pack NDC#: 59390-142-49 Product Size: 2 x 15 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18033	2/20	8/10/2018

Product Description: Nano Tears TF Clear Emollient Lubricant Gel Drops NDC#: 59390-142-13  
Product Size: 15 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18033	2/20	06/04/2018

Product Description: Nano Tears XP Clear Emollient Lubricant Gel Drops twin pack NDC#: 59390-143-51 Product Size: 2 x 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17366	12/19	1/31/2018

Product Description: Nano Tears XP Clear Emollient Lubricant Gel Drops NDC#: 59390-143-10  
Product Size: 10 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
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Lot Number	Expiration Date	Manufacturer Initial Ship Date
17366	12/19	1/5/2018
18103	/20	7/9/2018
18173	7/20	8/3/2018

Product Description: Altaire Ofloxacin 0.3% Ophthalmic Solution USP NDC#: 59390-140-05  
Product Size: 5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17244	8/19	10/9/2017
18057	3/20	5/15/2018
18307	12/20	1/9/2019

Product Description: ActivEyes Preservative Free Multi-Dose Lubricant Gel Drops Long Lasting  
PF NDC#: 59390-148-52 Product Size: 7.5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19015	1/21	4/2/2019

Product Description: ActivEyes Preservative Free Multi-Dose Lubricant Drops Sensitive PF  
NDC#: 59390-146-52 Product Size: 7.5 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18099	4/20	4/2/2019

Product Description: ActivEyes Lubricant Eye Ointment Preservative Free NDC#: 59390-189-  
50 Product Size: 3.5 gram

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SFE	06/21	4/23/2019

The foregoing products are manufactured and labeled by Altaire Pharmaceuticals, Inc. Altaire has notified all distributors by e-mail on July 15, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots. Any questions regarding this VOLUNTARY RECALL to the RETAIL LEVEL can be directed

to Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing [otcdruggist@aol.com](mailto:otcdruggist@aol.com) (mailto:otcdruggist@aol.com) Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET. Consumers 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/forms-reporting-fda>) 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.

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## Company Contact Information

### Consumers:

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### Media:

Michael Sawaya

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