**COMPANY ANNOUNCEMENT**

# Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens



## Summary

**Company Announcement Date:**

July 03, 2019

**FDA Publish Date:**

July 03, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

Potential for nonsterility

**Company Name:**

Altaire Pharmaceuticals, Inc.

**Brand Name:**

Walgreens

**Product Description:**

Eye drops and ophthalmic ointments

## Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the Over-the-Counter (OTC) drug products and lots, within expiry, sold at Walgreens 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 above. 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: Lubricant Eye Drops Moisturizing Walgreens item #: 801483 NDC #: 0363-0185-13 Package Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|---|---|---|
| 19095 | 04/21 | 05/14/19 |

Product Description: Lubricant Eye Drops Moisturizing Twin Pack Walgreens item #: 801477 NDC #: 0363-0185-49 Package Size: 2 x 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|---|---|---|
| 19095 | 04/21 | 05/14/19 |

Product Description: Sodium Chloride Ophthalmic Ointment, 5% Hypertonicity Eye Ointment Walgreens item #: 801482 NDC #: 0363-7500-50 Package Size: 3.5 gram

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|---|---|---|
| TCI | 03/21 | 05/08/2019 |

Product Description: Sodium Chloride Ophthalmic Solution, 5% Hypertonicity Eye Drops Walgreens item #: 801402 NDC #: 0363-0193-13 Package Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|---|---|---|
| 19105 | 04/22 | 05/24/2019 |
| 19050 | 02/22 | 05/23/2019 |

Product Description: Lubricant Eye Ointment PF Soothing Walgreens item #: 801486 NDC #: 0363-0191-50 Package Size: 3.5 gram

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|---|---|---|
| TDB | 04/22 | 05/24/2019 |

The products are manufactured and labeled exclusively for Walgreens. Altaire ships the products labeled for Walgreens only to Walgreens. The products are distributed at the retail level by Walgreens. Altaire has also requested that Walgreens notify its customers. Altaire has notified Walgreens by e-mail on July 3, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots.

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 through 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 (/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.

## Company Contact Information

**Consumers:**

Altaire Pharmaceuticals Inc.

1-800-258-2471

otcdruggist@aol.com (mailto:otcdruggist@aol.com)

**Media:**

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1-800-258-2471

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