



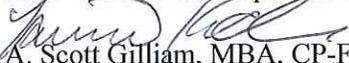
Indiana State
Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 9, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Altaire Pharmaceuticals Inc Recall [Drug]

AFFECTED PRODUCT Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution, 30 mL
Due to Complaints of Mold Found in the 30 mL Bottles After Use

SUGGESTED

ACTION: Unclassified Recall; Altaire Pharmaceuticals, Inc. announces today that it is voluntarily recalling a total of nine (9) lots of Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution, 30 mL, to the consumer level. The product is known generically as Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution and labeled as follows:

- equate Restore Tears Lubricant Eye Drops Carboxymethylcellulose Sodium 0.5%, Sterile, 1 FL OZ (30 mL) - Distributed by Wal-Mart Stores, Inc.;
- Lubricant EYE DROPS FOR MILD TO MODERATE DRY EYE, STERILE, 1 FL OZ (30 mL), for Mild to Moderate Dry Eye - Distributed by CVS Pharmacy, Inc.;
- lubricant eye drops for mild to moderate dry eye, STERILE, 1 FL OZ (30 mL) - Dist. by Target Corp.

Only the lots listed below are affected, and the recall is limited to the product in the 30 mL size:

- Lot # 11440, expiration date 09/2013, labeled for CVS;
- Lot # 11441, expiration date 09/2013, labeled for CVS;
- Lot # 12042, expiration date 01/2014, labeled for Wal-Mart and CVS;
- Lot # 12103, expiration date 02/2015, labeled for Wal-Mart;
- Lot # 12203, expiration date 05/2015, labeled for Wal-Mart and CVS;
- Lot # 12207, expiration date 05/2015, labeled for Wal-Mart;
- Lot # 12293, expiration date 08/2015, labeled for Wal-Mart;
- Lot # 12352, expiration date 09/2015, labeled for Target and CVS;
- Lot # 12356, expiration date 09/2015, labeled for Target and CVS.

Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution is a non-prescription (OTC) drug product used to relieve dryness of the eye and packaged in a plastic bottle inside a

unit box. Lot numbers can be found printed horizontally on the side of the label and on the bottom flap of the box. Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The lots listed above were distributed between February 2012 and April 2013. The product was sold nationwide at retail stores. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-3213.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Altaire Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of 9 Lots of Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution Sold Under Several Brands Because the Preservative May Not Be Effective Through Expiry

Contact:

Consumer:
Joseph Sawaya
(800) 258-2471

FOR IMMEDIATE RELEASE - September 06, 2013 – Aqueboque, NY, Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling a total of nine (9) lots of Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution, 30 mL, to the consumer level. There have been no reports of adverse effects to consumers so far. However, due to complaints of mold found in the 30 mL bottles after use, concerns regarding the effectiveness of the preservative after use and handling of the product by consumers have prompted the recall.

A product whose preservative may not be effective could lead to the use of a contaminated product which creates a potential risk for eye infection. It has been confirmed by Altaire that all lots of product were sterile at the time of release, and that the preservative was effective when challenged against the USP Preservative Effectiveness Test. It has also been confirmed by Altaire that its production facility is not the source of any reported contaminants.

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- Lot # 12207, expiration date 05/2015, labeled for Wal-Mart;
- Lot # 12293, expiration date 08/2015, labeled for Wal-Mart;
- Lot # 12352, expiration date 09/2015, labeled for Target and CVS;
- Lot # 12356, expiration date 09/2015, labeled for Target and CVS.

Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution is a non-prescription (OTC) drug product used to relieve dryness of the eye and packaged in a plastic bottle inside a unit box. Lot numbers can be found printed horizontally on the side of the label and on the bottom flap of the box. The lots listed above were distributed between February 2012 and April 2013. The product was sold nationwide at retail stores.

Altaire Pharmaceuticals is initiating the recall as a precautionary measure. Altaire takes its mission of consumer care and providing quality products very seriously. The company has reformulated the product with an enhanced preservative system. All lots of the product in the 30 mL size identified with lot numbers beginning with 13 (i.e. 13000) have been made with the enhanced preservative system.

Altaire Pharmaceuticals is notifying its customers of the recall by phone and letters for further notification to their retail stores. Consumers who have the product with any of the lot numbers listed above should stop use of the product immediately and return it to the place of purchase.

Consumers with questions regarding this recall can contact Altaire Pharmaceuticals at 1-800-258-2471, Monday – Friday from 9 am – 5 pm 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.

- **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form.

- Fax: 1-800-FDA-0178

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

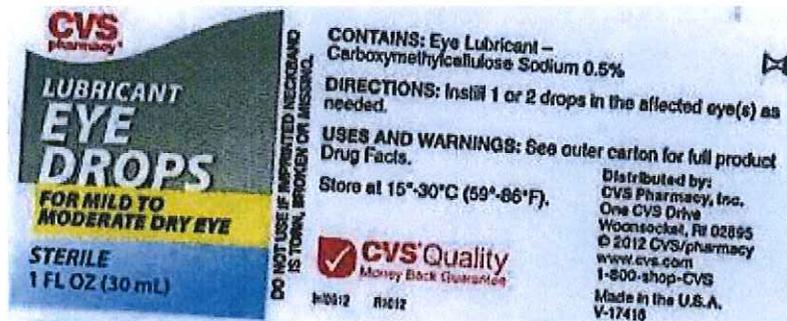
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RSS Feed for FDA Recalls Information³ [what's this?]⁴

Photo: Product Labels⁵

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.⁶

Altaire Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of 9 Lots of Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution Sold Under Several Brands Because the Preservative May Not Be Effective Through Expiry Photos



**lubricant
eye drops**



1 FL OZ (30 mL)



DO NOT USE IF IMPRINTED SEAL ON
CAP IS BROKEN, TORN OR MISSING.

CONTAINS: Eye Lubricant -
Carboxymethylcellulose Sodium 0.5%

DIRECTIONS: Instill 1 or 2 drops in the affected
eye(s) as needed.

USES AND WARNINGS: See outer carton for full
product Drug Facts.

Store at 15°-30°C (59°-86°F).

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Dist. by Target Corp., Mpls., MN 55403

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Shop Target.com

Guest Services 1-800-910-6874

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