

## Drug recall notice for: Multiple Ophthalmic Products Sold at CVS

- \*CVS Health Natural Tears Lubricant Eye Drops Preservative Free Item#: 538397 Product Size: 0.6 mL x 32 ct
- \*CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 317916 Product Size: 15 mL
- \*CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 247887 Product Size: 30 mL
- \*CVS Health Dry Eye Relief Eye Drops Item#: 317914 Product Size: 15 mL
- \*CVS Health Dry Eye Relief Eye Drops Item#: 457802 Product Size: 30 mL- Offered through our OTC Benefit
- \*CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495334 Product Size: 0.6 mL x 60 ct
- \*CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 994883 Product Size: 0.6 mL x 30 ct
- \*CVS Health Preservative Free Lubricant Gel Drops Dry Eye Relief Item#: 634634 Product Size: 0.6 mL x 30
- \*CVS Health Lubricating Gel Drops for Anytime Use Item#: 563420 Product Size: 10 mL
- \*CVS Health Overnight Lubricating Eye Ointment Item#: 881532 Product Size: 3.5 gram
- \*CVS Health Lubricant Eye Ointment Item#: 247881 Product Size: 3.5 gram
- \*CVS Health Extra Strength Lubricant Gel Drops Item#: 799143 Product Size: 15 mL
- \*CVS Health Extra Strength Lubricant Gel Drops Twin Pack Item#: 258587 Product Size: 2 x 15 mL
- \*CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Item#: 895160 Product Size: 15 mL
- \*CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Twin Pack Item#: 994881 Product Size: 2 x 10 mL
- \*CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495301 Product Size: 0.6 mL x 30ct
- \*CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 457791 Product Size: 0.6 mL x 70ct
- \*CVS Health Preservative Free Lubricant Eye Drops Advanced Relief Item#: 563442 Product Size: 0.6 mL x 30
- \*CVS Health Lubricant Eye Drops Advanced Relief Item#: 563419 Product Size: 10 mL
- \*CVS Health Fast Acting Lubricant Eye Drops Preservative Free Item#: 994882 Product Size: 0.6 mL x 24 ct
- \*CVS Health Preservative Free Lubricant Eye Drops Fast Acting Item#: 258625 Product Size: 0.6 mL x 60 ct
- \*CVS Health Lubricant Gel Drops-Moderate to Severe Dry Eye Relief Item#: 799145 Product Size: 30 mL
- \*CVS Health Multi-Action Relief Drops Item#: 694954 Product Size: 15 mL
- \*CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Item#:968210 Product Size: 10 mL
- \*CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Twin Pack Item#: 495323 Product Size: 2 x 10 mL
- \*CVS Health Maximum Redness Relief Eye Drops Item#: 994880 Product Size: 15 mL
- \*CVS Health Redness Relief Item#: 317912 Product Size: 15 mL
- \*CVS Health Redness Relief Item#: 457799 Product Size: 30 mL- Offered through our OTC Benefit
- \*CVS Health Lubricant Eye Drops Multi-Symptom Eye Relief Item#: 563431 Product Size: 15 mL
- \*CVS Health Lubricant Eye Ointment Sensitive Formula Item#: 247885 Product Size: 3.5 gram

Altaire Pharmaceuticals, Inc., announced that it is voluntarily recalling the Over-the-Counter (OTC) drug products and lots, within expiry, sold at CVS Health the during the time period as indicated in the tables below. As a precautionary measure, Altaire is voluntarily initiating the 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.

The above highlighted products are offered through our CVS OTC Benefit.

### What your patients should know:

They may be able to get the same medicine that is not part of the recall or switch to another medicine.

Please refer your patient to the FDA for the most current updates to this drug or have your patient ask their pharmacy for assistance. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/altaire-pharmaceuticals-inc-issues-voluntary-recall-multiple-ophthalmic-products-sold-cvs>

To determine if your patient's medicine is impacted, check the product name, manufacturer name and NDC. If the information is not listed (NDC or lot number), please contact the pharmacy that filled the prescription.

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:** Complete and submit the report: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular mail or fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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.

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### Voluntary Recall Letter:

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the Over-the-Counter (OTC) drug products and lots, within expiry, sold at CVS Health the during the time period as indicated in the tables below. As a precautionary measure, Altaire is voluntarily initiating the 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 at the chain store.

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 SPECIFICATIONS RESULTS, INCLUDING IN-HOUSE AND THIRD PARTY STERILITY TESTING, FOR THE PRODUCTS.

**Product Description: CVS Health Natural Tears Lubricant Eye Drops Preservative Free Item#: 538397**  
**Product Size: 0.6 mL x 32 ct**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SEI	5/21	06/20/2018
SGC	7/21	08/31/2018
QGB	07/19	09/06/2016
QID	09/19	11/11/2016
RJC	10/20	10/26/2017
RCJ	03/20	05/20/2017

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RCB	03/20	03/24/2017
TCJ	03/22	06/03/2019

**Product Description: CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 317916 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17196	08/19	10/13/2017
17192	09/19	11/14/2017
17355	11/19	12/22/2017
18024	01/20	02/27/2018
18036	02/20	03/26/2018
18237	09/20	10/31/2018
18293	12/20	12/27/2018
18105	04/20	06/06/2018
18179	07/20	08/08/2018
19040	2/21	03/26/2019

**Product Description: CVS Health Lubricant Eye Drops for Mild to Moderate Dry Eye Item#: 247887 Product Size: 30 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17222	07/19	09/28/2017
17386	12/19	01/15/2018
19018	01/21	03/14/2019
18016	01/20	02/19/2018
18181	07/20	08/27/2018
18104	04/20	06/08/2018
19018	1/21	06/04/2019

**Product Description: CVS Health Dry Eye Relief Eye Drops Item#: 317914 Product Size: 15 mL**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17215	07/19	08/23/2017
17239	08/19	01/02/2018
18081	03/21	04/25/2018
18207	08/20	09/04/2018
18274	11/21	11/27/2018

**Product Description: CVS Health Dry Eye Relief Eye Drops Item#: 457802 Product Size: 30 mL**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17277	09/19	10/20/2017
18006	01/20	02/22/2018
18098	04/21	02/04/2019
18006	1/20	05/30/2018
19057	02/22	03/29/2019

**Product Description: CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495334  
Product Size: 0.6 mL x 60 ct**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
RGF	07/19	08/10/29017
RHN	08/19	09/29/2017
RIH	09/19	10/30/2017
RJP	10/19	11/30/2017
RKN	11/19	12/11/2017
SDC	04/20	05/10/18
SFC	06/20	06/28/18
SFJ	06/20	07/25/18
SGI	07/20	09/18/18

**Product Description: CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 994883**  
**Product Size: 0.6 mL x 30 ct**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RGF	07/19	08/10/2017
RHN	08/19	09/29/2017
RIH	09/19	10/23/2017
RJP	10/19	11/30/2017
RKN	11/19	12/11/2017
SDC	04/20	05/10/2018
SFC	06/20	06//28/2018
SFJ	06/20	07/25/2018
SGI	07/20	10/09/2018
SKF	11/20	01/04/2019
TAE	01/21	01/04/2019

**Product Description: CVS Health Preservative Free Lubricant Gel Drops Dry Eye Relief Item#: 634634**  
**Product Size: 0.6 mL x 30**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SEI	5/20	06/20/2018
TAK	01/21	02/28/2019

**Product Description: CVS Health Lubricating Gel Drops for Anytime Use Item#: 563420 Product Size: 10 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17238	08/19	10/24/2017
18094	4/20	8/10/2018
19058	02/21	03/25/2019

**Product Description: CVS Health Overnight Lubricating Eye Ointment Item#: 881532 Product Size: 3.5 gram**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RJK	10/19	12/21/2017

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SBJ	2/20	03/12/2018
SFG	6/20	07/19/2018
SHI	8/20	11/06/2018
SLB	12/20	02/01/2019
TCM	03/21	04/30/2019
TDC	4/21	03/20/2019

**Product Description: CVS Health Lubricant Eye Ointment Item#: 247881 Product Size: 3.5 gram**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
SAS	1/21	08/9/2018
SIA	9/21	02/28/2019
SFE	6/21	11/14/2018
SAS	1/21	08/9/2018
SFE	6/21	11/14/2018
SIA	9/21	02/28/2019
RIE	9/20	01/9/2018
REH	5/20	07/17/2018
RAD	1/20	05/4/2017
TAH	01/22	03/11/2019

**Product Description: CVS Health Extra Strength Lubricant Gel Drops Item#: 799143 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19087	3/21	04/26/2019
17289	9/19	12/19/2017
19087	03/21	04/26/2019
18122	5/20	11/19/2018

**Product Description: CVS Health Extra Strength Lubricant Gel Drops Twin Pack Item#: 258587 Product Size: 2 x 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19087	03/21	05/29/2019
18122	5/20	11/19/2018
17289	9/19	04/20/2018

**Product Description: CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Item#: 895160 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17223	07/19	09/26/2017
17297	10/19	11/17/2017
18017	01/20	02/05/2018
18018	01/20	02/21/2018
18065	03/21	06/08/2018
18213	08/20	09/11/18
18247	10/21	11/01/18

**Product Description: CVS Health Fast Acting Lubricant Eye Drops Dry Eye Therapy Twin Pack Item#: 994881 Product Size: 2 x 10 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17296	10/19	07/23/2017
18094	04/20	05/11/2018
18206	08/20	09/06/2018

**Product Description: CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 495301 Product Size: 0.6 mL x 30ct**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
QHI	08/19	11/18/2016
QJG	10/19	12/6/2016
RBA	02/20	03/08/2017
RCF	03/20	04/11/2017

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RCM	03/20	04/28/2017
RDJ	04/20	06/01/2017
RFA	06/20	06/20/2017
RHI	08/20	09/28/2017
RJI	10/20	11/16/2017
RKG	11/20	12/08/2017
SBF	2/21	06/6/2018
SDD	04/21	05/23/2018

**Product Description: CVS Health Preservative Free Lubricant Eye Drops Sensitive Solution Item#: 457791**  
**Product Size: 0.6 mL x 70ct**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
QHF	08/19	10/20/2016
QHI	08/19	11/10/2016
QLA	12/19	01/05/2017
RBA	02/20	03/07/2017
RCF	03/20	04/11/2017
RCM	03/20	04/28/2017
RDJ	04/20	06/01/2017
RFA	06/20	06/21/2017
RHI	08/20	09/28/2017
RJI	10/20	11/16/2017
RKG	11/20	01/02/2018
RLE	12/20	01/02/2018
SAE	01/21	02/14/2018
SBF	02/21	04/11/2018



**Product Description: CVS Health Preservative Free Lubricant Eye Drops Advanced Relief Item#: 563442**  
**Product Size: 0.6 mL x 30**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
RJM	10/19	11/22/2017
RIA	09/19	10/04/2017
SAN	01/20	02/22/2018
SFF	06/20	08/02/2018

**Product Description: CVS Health Lubricant Eye Drops Advanced Relief Item#: 563419 Product Size: 10 mL**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
17285	09/19	01/03/2018
18067	03/20	05/02/2018
18205	08/20	08/30/2018
18067	3/20	05/03/2018

**Product Description: CVS Health Fast Acting Lubricant Eye Drops Preservative Free Item#: 994882 Product Size: 0.6 mL x 24 ct**

<b>Lot Number</b>	<b>Expiration Date</b>	<b>Manufacturer Initial Ship Date</b>
RIN	09/19	10/23/2017
RKP	11/19	01/02/2018
SAR	01/20	03/07/2018
SCG	03/20	04/17/2018
SED	5/20	06/07/2018
SLC	12/20	01/18/2019
TBE	02/21	04/01/2019
TBL	02/21	05/15/2019

**Product Description: CVS Health Preservative Free Lubricant Eye Drops Fast Acting Item#: 258625 Product Size: 0.6 mL x 60 ct**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
RHD	08/19	08/29/2017
RIF	09/19	10/17/2017
RIN	09/19	10/23/2017
RKP	11/19	01/08/2018
SAR	01/20	02/21/2018
SCG	03/20	04/17/2018
SED	5/20	06/7/2018

**Product Description: CVS Health Lubricant Gel Drops-Moderate to Severe Dry Eye Relief Item#: 799145  
Product Size: 30 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17214	07/19	09/29/2017
18002	1/20	11/14/2018
18113	5/20	02/4/2019

**Product Description: CVS Health Multi-Action Relief Drops Item#: 694954 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16267	10/19	11/07/2016
18096	04/21	08/01/2018
18301	12/21	12/27/2018
18096	4/21	06/14/2018
18301	12/21	12/27/2018
17371	12/20	01/19/2018
17158	6/20	06/26/2017
17025	1/20	04/21/2017
17015	1/20	02/08/2017

Lot Number	Expiration Date	Manufacturer Initial Ship Date
19103	04/22	06/03/2019

**Product Description: CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Item#:968210 Product Size: 10 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17291	9/19	12/15/2017
17385	12/19	07/10/2018
18118	5/20	09/18/2018
18266	10/20	12/11/2018

**Product Description: CVS Health Lubricant Eye Drops Lasting Dry Eye Relief Twin Pack Item#: 495323 Product Size: 2 x 10 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17291	9/19	12/19/2017
17385	12/19	03/23/2018
18118	5/20	08/17/2018

**Product Description: CVS Health Maximum Redness Relief Eye Drops Item#: 994880 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17251	8/19	09/05/2017
17269	9/19	11/09/17
17360	12/19	01/10/2018
18012	1/20	04/20/2018
18106	4/20	05/24/2018
18275	11/20	12/05/2018
18275	11/20	12/06/2018

**Product Description: CVS Health Redness Relief Item#: 317912 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18229	9/21	10/12/18

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18031	1/21	04/10/2018
17131	5/20	06/19/2017
17059	3/20	06/20/2017
17008	1/20	02/01/2017
19056	03/22	05/01/2019

**Product Description: CVS Health Redness Relief Item#: 457799 Product Size: 30 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18229	9/21	11/02/2018
18229	9/21	06/04/2019
19056	03/22	04/17/2019

**Product Description: CVS Health Lubricant Eye Drops Multi-Symptom Eye Relief Item#: 563431 Product Size: 15 mL**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
18043	2/20	03/16/2018
18115	5/20	08/06/2018
18300	12/20	02/01/2019
18300	12/20	02/01/2019
18116	5/20	02/01/2019
18115	5/20	06/11/2018
18044	2/20	05/30/2018
18043	2/20	03/16/2018

**Product Description: CVS Health Lubricant Eye Ointment Sensitive Formula Item#: 247885 Product Size: 3.5 gram**

Lot Number	Expiration Date	Manufacturer Initial Ship Date
QHE	08/19	11/11/2016
QJD	10/19	01/16/2017

The products are manufactured and labeled exclusively for CVS Health. Altaire ships the products labeled for CVS only to CVS. The products are distributed at the retail level by CVS. Altaire has notified CVS by e-mail on July 10, 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) 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](#)
- Regular Mail or Fax: [Download form](#) 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:**

Altaire Pharmaceuticals Inc.

1-800-258-2471

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