Cardinal Health, Inc. Issues Voluntary Nationwide Recall of Certain LEADER™ Brand Eye Drops Supplied by Velocity Pharma, LLC Due to Potential Risk of Eye Infections

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FOR IMMEDIATE RELEASE – October 31, 2023 – Dublin, OH, Cardinal Health, Inc. is initiating a voluntarily recall for all lots of ophthalmic products supplied by Velocity Pharma, LLC to the consumer level. Cardinal Health, Inc. received information from FDA indicating investigators found insanitary conditions in the manufacturing facility and positive bacterial test results from environmental sampling of critical drug production areas in the facility.

Risk Statement: For those patients who use these products, there is a potential risk of eye infections that could result in partial vision loss or blindness. These products are intended to be sterile. Ophthalmic drug products pose a potential heightened risk of harm to users because drug applied to the eyes bypass some of the body's natural defenses. To date, Cardinal Health, Inc., and its subsidiaries have received reports of three (3) adverse events related to these listed products. The reports of adverse events were shared with our supplier, Velocity Pharma, LLC.

These products are available as over the counter (OTC) products used for temporary relief of burning and irritation due to dryness of the eye, for use as a protectant against further irritation or to relieve dryness of the eye, and/or to relieve redness of the eye due to minor eye irritations.

These products can be identified on the outer carton labeling as follows:

Product Name	Package Description	Brand Name	NDC
Eye Irritation Relief (Polyvinyl Alcohol, 0.5%, Povidone, 0.6%, and Tetrahydrozoline Hydrochloride, 0.05%)	0.5 FL OZ bottle (15 mL)	LEADER™	70000-0087-1
Dry Eye Relief (Carboxymethylcellulose Sodium, 1%)	0.5 FL OZ bottle (15 mL)	LEADER™	70000-0089-1
Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%)	0.5 FL OZ bottle (15 mL)	LEADER™	70000-0090-1
Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%)	2 bottles, 0.5 FL OZ (15 mL) each	LEADER™	70000-0090-2 (Carton) 70000-0090-1 (Bottle)
Dry Eye Relief (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%)	0.33 FL OZ bottle (10 mL)	LEADER™	70000-0088-1
Lubricant Eye Drops (Propylene Glycol, 0.6%)	0.33 FL OZ bottle (10 mL)	LEADER™	70000-0587-1

Images of the outer carton labeling of these listed products can be found below.

Products were distributed Nationwide to Wholesalers and Retailers starting December 12, 2021.

Cardinal Health, Inc. is notifying all impacted direct accounts via mail of this voluntary recall and is arranging for return of all recalled products listed above. Wholesalers, Distributors and Retailers that have the affected product which is being recalled should cease distribution of the products. Consumers should stop using the recalled eye drop products and may return any of the above listed products to the place of purchase.

Consumers with questions regarding this recall can contact Sedgwick, Inc. by phone at 1-855-215-4940 (8:00am-5:00pm EST Monday through Friday) or by email at Cardinalhealth7720@sedgwick.com. Consumers who have signs or symptoms of an eye infection after using these products should talk to their health care provider or seek medical care immediately.

Adverse reactions or quality problems experienced with the use of these products 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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form 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

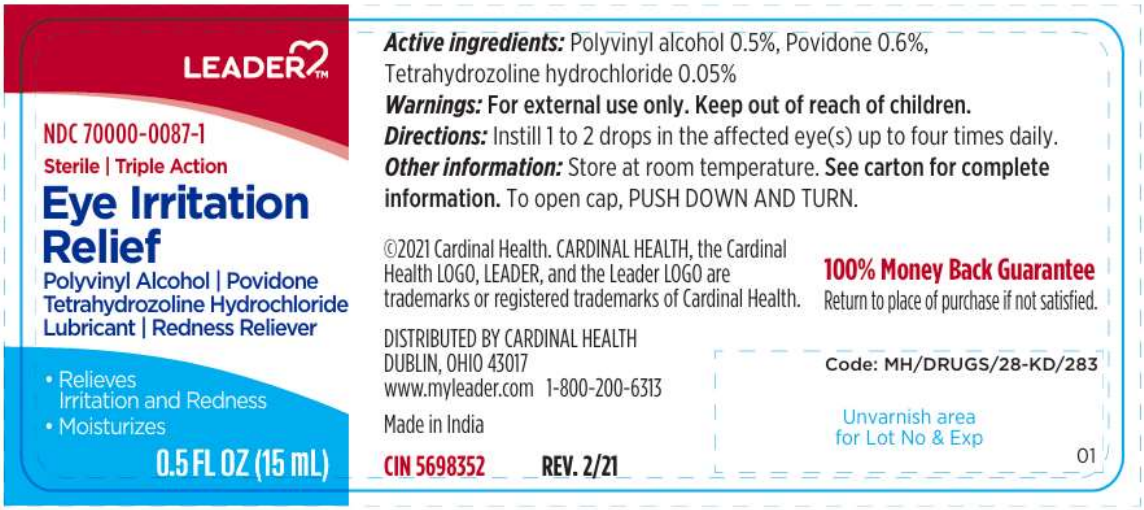
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Product Photographs:

Eye Irritation Relief (Polyvinyl Alcohol, 0.5%, Povidone, 0.6%, and Tetrahydrozoline Hydrochloride, 0.05%), NDC 70000-0087-1

Carton:

Bottle:



Dry Eye Relief (Carboxymethylcellulose Sodium, 1%), NDC 70000-0089-1

Carton:

Bottle:

Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%), NDC 70000-0090-1

Carton:

Bottle:

Lubricant Eye Drops (Carboxymethylcellulose Sodium, 0.5%), NDC 70000-0090-2 (Carton); NDC 70000-0090-1 (Bottle)

Carton:

Bottle:

Dry Eye Relief (Polyethylene Glycol 400, 0.4% and Propylene Glycol, 0.3%), NDC 70000-0088-1

Carton:

Bottle:

Lubricant Eye Drops (Propylene Glycol, 0.6%), NDC 70000-0587-1

Carton:

Bottle: