

Recall of over-the-counter (OTC) eye drops

- On October 31, 2023, <u>Cardinal Health</u> and <u>Harvard Drug Group announced</u> a consumer level recall
 of all lots of over-the-counter (OTC) ophthalmic products supplied by Velocity Pharma. Both
 companies received information from the FDA indicating investigators found insanitary conditions in
 the manufacturing facility and positive bacterial test results from an environmental sampling of
 critical drug production areas in the facility.
- The following Cardinal Health products were shipped nationwide starting December 12, 2021.

Product Description	Package Description	NDC Number
Eye Irritation Relief (polyvinyl alcohol/ 0.5%/povidone, 0.6%/ tetrahydrozoline hydrochloride, 0.05%)	0.5 FL oz. bottle (15 mL)	70000-0087-1
Dry Eye Relief (carboxymethylcellulose sodium, 1%)	0.5 FL oz. bottle (15 mL)	70000-0089-1
Lubricant Eye Drops (carboxymethylcellulose sodium, 0.5%)	0.5 FL oz. bottle (15 mL)	70000-0090-1
Lubricant Eye Drops (carboxymethylcellulose sodium, 0.5%)	2 bottles, 0.5 FL Oz. (15 mL) each	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)	70000-0088-1
Lubricant Eye Drops (propylene glycol, 0.6%)	0.33 FL oz. bottle (10 mL)	70000-0587-1

The following Harvard Drug Group products were distributed nationwide starting June 1, 2021:

Product Description	Package Description	NDC Number
Polyvinyl Alcohol, 1.4% Lubricating Eye Drops	0.5 FL oz. bottle (15 mL)	0536-1325-94
Lubricating Tears Eye Drops (dextran/hypromellose 0.1%/0.3%)	0.5 FL oz. bottle (15 mL)	0536-1282-94

- These OTC eye drops are 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.
- Using recalled OTC eye drops may lead to eye infections that could result in partial vison loss or blindness. These products are intended to be sterile. Ophthalmic drug products pose a potential heightened risk of harm to users because drugs applied to the eyes bypass some of the body's natural defenses.
- To date, Cardinal Health and Harvard Drug Group received reports of adverse events related to the recalled products.
- Anyone with the affected products on hand should stop distribution and return product. Consumers should stop use and return the product to their place of purchase. Consumers should contact their healthcare provider or seek immediate medical attention if they have experienced any signs or symptoms of an eye infection after using these products.
- Contact Sedgwick for more information about these recalls:
 - Sedgwick (appointed company for Cardinal) by phone at 1-855-215-4940 or by email at Cardinalhealth7720@sedgwick.com
 - Contact Sedgwick (appointed company for Harvard Drug Group) by phone at 1-866-891-1981 or by email at harvarddrug8430@sedgwick.com



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