The Harvard Drug Group, LLC Issues Voluntary Nationwide Recall of Certain Rugby® Laboratories 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 – La Vergne, TN, The Harvard Drug Group, LLC d/b/a Major® Pharmaceutical and Rugby® Laboratories is initiating a voluntarily recall for all lots of Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%) supplied by Velocity Pharma, LLC to the consumer level. The Harvard Drug Group, LLC received information from FDA indicating investigator 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 of 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. The Harvard Drug Group, LLC has received three (3) reports of adverse events related to these products including reports of vision blurriness, vision loss, and burning eyes. The reports of adverse events were shared with our supplier, Velocity Pharma, LLC.

Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%) are available as over the counter (OTC) products used for temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun and the product used as a protectant against further irritation or to relieve dryness of the eye.

Both Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%) can be identified on the outer carton labeling as follows:

Brand Name	Product Name	Package Description	NDC
Rugby®	Polyvinyl Alcohol, 1.4% Lubricating Eye Drops	0.5 oz bottle (15 mL)	0536-1325-94
Rugby®	Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)	0.5 oz bottle (15 mL)	0536-1282-94

Images of the outer carton labelling of both Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%) can be found below.

Products were distributed Nationwide starting June 1, 2021.

The Harvard Drug Group, LLC 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 1-866-891-1981 (8:00am-5:00pm EST Monday through Friday) or by email address harvarddrug8430@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:

Polyvinyl Alcohol, 1.4% Lubricating Eye Drops, NDC 0536-1325-94

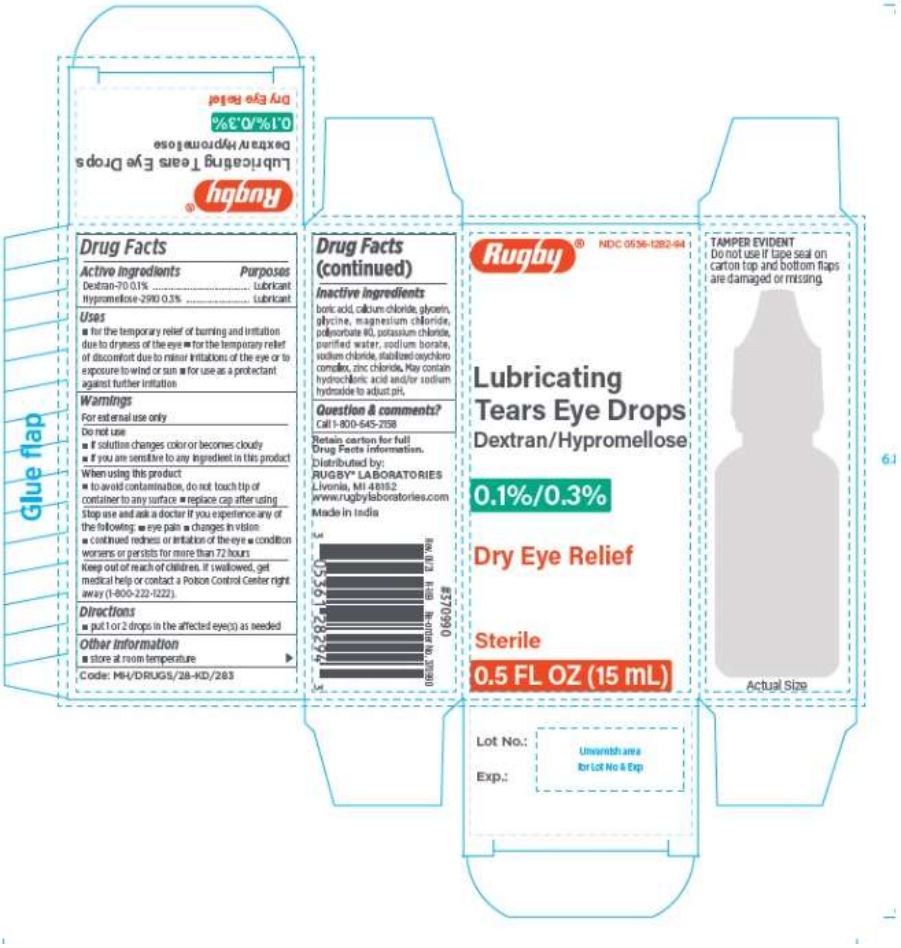
Carton:

Bottle:

Product Photographs:

Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%), NDC 0536-1282-94

Carton:



Bottle:

Rugby
Lubricating
Tears Eye Drops
Dextran/Hypromellose
0.1%/0.3%
Dry Eye Relief
Sterile
0.5 FL OZ (15 mL)
Active Ingredients: Dextran-70 0.1% (Lubricant), Hypromellose-2910 0.3% (Lubricant).
Uses: For the temporary relief of burning and irritation due to dryness of the eye and for use as a protectant against further irritation. For the temporary relief of discomfort due to minor irritation of the eye or to exposure to wind or sun.
Directions: Put 1 or 2 drops in the affected eye(s) as needed.
Warnings: If solution changes color or becomes cloudy, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using. Keep this and all drugs out of the reach of children. See carton for complete Warnings.
TAMPER EVIDENT: For your protection, Do not use if tamper seal ring on bottle neck is damaged or broken. Store at room temperature.
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www.rugbylaboratories.com Made in India
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Code: MH/DRUGS/28-KD/283
Lot:
Exp:
Unvarnish area for Lot No & Exp