

COMPANY ANNOUNCEMENT

Global Pharma Healthcare Issues Voluntary Nationwide Recall of Artificial Tears Lubricant Eye Drops Due to Possible Contamination

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

February 02, 2023

FDA Publish Date:

February 02, 2023

Product Type:

Drugs

Reason for Announcement:

Potential microbial contamination

Company Name:

Global Pharma Healthcare

Brand Name:

EzriCare & Delsam Pharma

Product Description:

Artificial Tears Lubricant Eye Drops

Company Announcement

Global Pharma Healthcare is voluntarily recalling all lots within expiry of their **Artificial Tears Lubricant Eye Drops, distributed by /EzriCare, LLC- and Delsam Pharma**, to the consumer level, due to possible contamination. The Centers for Disease Control and Prevention (CDC) alerted FDA to an investigation of a multi-state cluster of Verona Integron-

mediated Metallo- β -lactamase (VIM)- and Guiana-Extended Spectrum- β -Lactamase (GES)-producing carbapenem-resistant *Pseudomonas aeruginosa* (VIM-GES-CRPA) infections possibly associated with the use of the artificial tears manufactured by Global Pharma Healthcare. To date, there are 55 reports of adverse events including eye infections, permanent loss of vision, and a death with a bloodstream infection.

Risk Statement: Use of contaminated artificial tears can result in the risk of eye infections that could result in blindness.

Artificial Tears (carboxymethylcellulose sodium) Lubricant Eye Drops, 10 mg in 1 mL, 1/2 fl oz (15 ml) bottle are used as a protectant against further irritation or to relieve dryness of the eye for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun. The product is packaged in a bottle with a safety seal and are placed in a carton box Ezricare NDC 79503-0101-15, UPC 3 79503 10115 7; Delsam Pharma's NDC 72570-121-15, UPC -72570-0121-15. It can be identified by the photos below. The product was distributed Nationwide in the USA over the Internet.

Global Pharma Healthcare is notifying the distributors of this product, Aru Pharma Inc. and Delsam Pharma and is requesting that wholesalers, retailers and customers who have the recalled product should stop use.

Consumers with questions regarding this recall can contact the distributors: Aru Pharma/Ezricare, LLC - by phone: 1-518-738-7602 or by e-mail: arupharmainc@yahoo.com (<mailto:arupharmainc@yahoo.com>) from Monday to Friday, 11am to 4pm EST; or DELSAM Pharma LLC by phone: 1-866-826-1309 or by e-mail: delsampharma@yahoo.com (<mailto:delsampharma@yahoo.com>) from Monday to Friday from 11am to 4pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these over-the-counter drug products.

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 \(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\)](/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: [Download form \(/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting\)](/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

Company Contact Information

Consumers:

DELSAM Pharma LLC.

☎ 1-866-826-1309

✉ delsampharma@yahoo.com (<mailto:delsampharma@yahoo.com>)

Product Photos





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