

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

Company Contacts:

Aru Pharma/EzriCare, LLC: Phone Number 1-516-715-5181

Delsam Pharma: Mr. Kuppusamy Arumugam
Phone Number 1-866-826-1306



FOR IMMEDIATE RELEASE – February 2, 2023 – 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, ½ 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 -3 72570 12115 8. 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: 1-516-715-5181 or by e-mail: arupharmainc@yahoo.com from Monday to Friday, 11am to 4pm EST; or DELSAM Pharma LLC by phone: 1-866-826-1306 or by e-mail: 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:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm² 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.

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

Company Contacts:

Delsam Pharma: Phone Number 1-866-826-1306

FOR IMMEDIATE RELEASE –February 24, 2023 – Global Pharma Healthcare is voluntarily recalling Batch No (H29) of their **Artificial Eye Ointment** , distributed by **Delsam Pharma**, to the **consumer** level. .FDA informed that few product is leaking when the cap is opened, FDA recommends this may cause bacterial contamination

Risk Statement:

The Artificial Eye Ointment is suspected to have potential bacterial contamination (Not specified)

Use of contaminated artificial eye ointment can result in the risk of eye infections

To date, Global Pharma Healthcare has not received any reports of adverse events related to this recall.

Artificial Eye Ointment (Mineral Oil 15%,White Petrolatum 83%) Lubricant Eye Ointment, (3.5 grams,1/8 Oz) is used as eye lubricant and to relieve dryness of the eyes. The product is packaged in a aluminum tube and placed in a carton box. Delsam Pharma's NDC 72570-122-35, UPC – 3 72570 12235 3 . It can be identified by the photos provided below. The product was distributed Nationwide in the USA over the Internet.

Global Pharma Healthcare is notifying the Brand Owner/Importer of this product, 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: DELSAM Pharma LLC by phone: 1-866-826-1306 or by e-mail: 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:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm² 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

**ARTIFICIAL
EYE
OINTMENT**

**SPL UNCLASSIFIED
SECTION**

Drug Facts

ACTIVE INGREDIENT
Mineral Oil 15%
White Petrolatum 83%

PURPOSE
Eye lubricant
Eye lubricant

USES
For use as a lubricant to prevent further irritation or to relieve dryness of the eyes.

WARNINGS

- For external use only.
- To avoid contamination, do not touch tip of container to any surface.
- Replace cap after using.

Stop use and ask a doctor if
you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours.

Keep out of the reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

**Delsam Pharma's
ARTIFICIAL EYE OINTMENT**

Sterile

FOR OPHTHALMIC USE ONLY
Net Wt. 3.5 g (1/8oz.)

READ OUTER CARTON FOR INFORMATION BEFORE USING

ACTIVE INGREDIENT: Mineral Oil 15% and White Petrolatum 83%

Inactive ingredient: Lanolin 2%. **INDICATIONS:** For use as a lubricant to prevent further irritation or relieve dryness of the eyes. **DIRECTIONS:** Pull down lower lid of the affected eye(s) and apply small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor.

STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP controlled Room Temperature].

WARNING: Keep out of the reach of children.
DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

Distributed by:  **Delsam Pharma Inc**, Bronx, Newyork 10467.

Drug Facts
(continued)

DIRECTIONS
Pull down lower lid of the affected eye(s) and apply small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor.

OTHER INFORMATION

- Store at 20° to 25°C (68° to 77°F) [see USP controlled Room Temperature].
- Store away from heat.
- Protect from freezing.
- Keep tightly closed.
- See crimp for Control Number and Expiration Date.
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

INACTIVE INGREDIENT
Lanolin 2%

Questions or comments?
1-866-626-1309 between 9am and 4 pm EST, Monday-Friday.

**ARTIFICIAL
EYE
OINTMENT**

**Delsam Pharma's
ARTIFICIAL EYE OINTMENT**

Sterile

FOR OPHTHALMIC USE ONLY
Net Wt. 3.5 g (1/8oz.)

NDC 72570 122 35

Lot No. :
Exp. Date :

Manufactured by:
Delsam Pharma Inc
Bronx, Newyork 10467.