Delsam Pharma LLC Issues Voluntary Nationwide Recall of Artificial Eye Ointment and Artificial Tears Due to Possible Microbial Contamination

Summary

Company Announcement Date:
February 23, 2023

Company Announcement

FOR IMMEDIATE RELEASE - February 23, 2023, Delsam Pharma LLC is voluntarily recalling Batch No. H29 of Artificial Eye Ointment, distributed to the consumer level. FDA informed the manufacturer Global Pharma Healthcare Pvt. Ltd. that a few pieces were leaking when the cap was opened. FDA mentions that this may cause bacterial contamination.

Delsam Pharma LLC previously voluntarily recalled Artificial Tears on January 31, 2023, out of an abundance of caution. This was at the request of the manufacturer, Global Pharma Healthcare Pvt. Ltd. Global Pharma Healthcare Pvt. Ltd. previously voluntarily recalled Batch No. H29 of Artificial Eye Ointment on February 2, 2023. Please stop use of both products immediately.

Risk Statement: The Artificial Eye Ointment is suspected to have potential bacterial contamination (Not specified). Use of contaminated eye ointment can result in the risk of eye infections.

Artificial Eye Ointment (mineral oil 15%, white petrolatum 83%, 3.5 grams / 1/8 oz.) is used as an eye lubricant and to relieve dryness of the eyes. The product is packaged in a white aluminum tube within a paper carton. The product can be identified by the photos provided below. The product was distributed nationwide in the United States by Delsam through internet retail sites. Delsam Pharma's NDC for this product is 72570-122-35, and its UPC code is 3 72570 12235 3.

Artificial Tears Lubricated Eye Drops (**ACTIVE INGREDIENTS:** Carboxymethylcellulose Sodium 10 MG in 1 ml. **INACTIVE INGREDIENTS:** Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide, and water for injection) is 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. It has a safety seal top that is required to be broken by the user in order to be used.

Delsam Pharma is requesting that all customers who have the recalled products should stop any use and discard the product safely and appropriately.

Delsam Pharma is not associated with any other labeler/distributor company.

Consumers with questions regarding this recall can contact the distributor Delsam Pharma, LLC by phone at 1-866-826-1306 or by e-mail at 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.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.

Company Contact Information

Consumers:

distributor Delsam Pharma, LLC
1-866-826-1306
delsampharma@yahoo.com

Outer package label

Inner package label