Global Pharma Healthcare – Recall of Artificial Tears Lubricant Eye Drops

- On February 2, 2023, Global Pharma Healthcare announced a consumer-level recall of all lots within expiry of their Artificial Tears Lubricant Eye Drops, distributed by EzriCare and Delsam Pharma due to possible contamination.

    — Clinical Services will send notifications to members and their prescribers potentially impacted by this recall.
    — The member letters advise members to stop use of the recalled product and contact their pharmacy or place of purchase for a replacement. Members may also contact their healthcare provider about alternative treatment options.
    — Other artificial tear products made by other manufacturers that are not being recalled are available for patients to use.

- The FDA is warning consumers and healthcare providers not to purchase and immediately stop using EzriCare Artificial Tears or Delsam Pharma¨—s Artificial Tears.

- To date, there are 55 reports of adverse events including eye infections, permanent loss of vision, and a death with a bloodstream infection.

- The recalled product was distributed nationwide over the internet.

Product Description	NDC#	Lot# (Expiration Date)
Ezricare Artificial Tears (carboxymethylcellulose sodium) Lubricant Eye Drops, ¨φ fl. oz. (15 mL)	79503-0101-15	All lots within expiry
Delsam Pharma¨—s Artificial Tears (carboxymethylcellulose sodium) Lubricant Eye Drops, ¨φ fl. oz. (15 mL)	72570-121-15	

- Artificial Tears (carboxymethylcellulose sodium) lubricant eye drops 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 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.

- The FDA recommended this recall due to manufacturing violations, including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging.

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- Using contaminated artificial tears increases risk of eye infections that could result in blindness or death. Patients who have signs or symptoms of an eye infection should talk to their health care provider or seek medical care immediately.

    — Eye infection symptoms may include discharge from the eye, eye pain or discomfort, redness of the eye or eyelid, foreign body sensation in the eye, increased sensitivity to light, or blurry vision.

- Patients who are currently using the recalled artificial tears should stop use and contact their pharmacy or place of purchase for a replacement. Patients 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.

- If patients were advised to use EzriCare or Delsam Pharma˜—s Artificial Tears by their healthcare provider, they should follow up with their healthcare provider for recommendations about alternative treatment options.

- Anyone with an existing inventory of the recalled product should stop use, distribution, and quarantine the product immediately and arrange for return.

- Contact Aru Pharma/Ezricare by phone at 1-518-738-7602 or by e-mail at **arupharmainc@yahoo.com** or Delsam Pharma by phone at 1-866-826-1309 or by e-mail at **delsampharma@yahoo.com** for questions regarding this recall.

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