

PharMerica

CDC Warns: Infection Risk Associated with Certain Artificial Tears and Ointment Continues

Past Issue

PharMerica published a <u>Clinical Advisory</u> in February 2023, shortly before the <u>voluntary nationwide recall of EzriCare</u> <u>Artificial Tears Lubricant Eye Drops</u> was issued by Global Pharma Healthcare (now updated to include alternative brand name – Delsam Pharma Artificial Tears).

This recall came on the heels of the CDC urging clinicians and patients to halt use of these products pending investigation into multi-state infection outbreaks causing permanent vision loss, hospitalization and one death. Specifically, the CDC investigation focuses on epidemiology and laboratory evidence linking the infections to the Global Pharma Healthcare products and possible contamination with *P. aeruginosa* – a bacteria notably causative to healthcare associated infections.

Global Pharma Healthcare also agreed to a <u>second voluntary consumer-level recall of Delsam Pharma's Artificial Eye</u> <u>Ointment</u>, due to possible microbial contamination.

Current Update

The <u>CDC states</u> that, as of March 14, 2023, 68 patients have been identified in 16 states with a rare strain of extensively drug-resistant *P. aeruginosa* (**VIM-GES-CRPA**). 37 patients were linked to 4 healthcare facility clusters. 3 people have died, there have been 8 reports of vision loss and 4 reports of enucleation (surgical removal of eyeball).

Most patients used eye drops, with over 10 brands of artificial tears reported and some patients used multiple brands. **EzriCare Artificial Tears**, a preservative-free, over-the-counter product packaged in multidose bottles, was the brand most commonly reported. This was the only common artificial tears product identified across the 4 healthcare facility clusters.

Patients and healthcare providers should immediately stop the use of EzriCare/Delsam Pharma's Artificial Tears and Delsam Pharma's Artificial Eye Ointment pending additional information and guidance from CDC and FDA.

Products Affected

- EzriCare[™] Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium, 10mg in 1mL) in ½ fl. oz (15mL) containers (NDC: 79503-0101-15).
- Delsam Pharma's Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium, 10mg in 1mL) in ½ fl. oz (15mL) containers (NDC: 72570-121-15).
- Delsam Pharma's Artificial Eye Ointment (mineral oil 15%, white petrolatum 83%, 3.5gm / 1/8 oz.) (NDC: 72570-122-35)







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Action Steps

PharMerica Pharmacies

- Note: Company-wide purchase history shows NO purchases of these 3 affected products through October 2022.
- If orders for affected products were sent to facilities, pharmacy to pick up the affected products.
- Check current inventory for affected products and quarantine to prevent dispensing, pending further CDC/FDA info.
- Halt future orders for affected products and continue to monitor for further guidance from CDC/FDA.

Facilities

- Check on-hand stock for affected products provided from PharMerica and from other vendors.
- Remove affected products from all areas and segregate for return to the originating vendor (PharMerica or other pharmacy) and notify that vendor of any stock for pick up.
- Monitor residents who have administered EzriCare or Delsam Pharma eye drops/ointment for signs/symptoms of ophthalmic infection and perform culture/antimicrobial susceptibility testing when clinically indicated.
- Check residents treated for keratitis or endophthalmitis for use of these identified products.
- At time of this publication, there is no recommendation for testing of patients who have used these products and who are NOT experiencing any signs or symptoms of infection.
- If adverse reactions or infections are experienced with the use of these products, submit a report online to: www.fda.gov/medwatch/report.htm
- Consult with a specialist knowledgeable in the treatment of antibiotic-resistant bacteria to determine the best treatment option for any positive cases of VIM-GES-CRPA infection in your facility.
- Refer to these <u>specific CDC infection control recommendations</u> (under Clinical Information) for positive cases, to prevent transmission across patients, as these bacteria have the potential to spread rapidly in healthcare settings.