NEW MEXICO
Department of Health
Epidemiology And Response Division

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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

FDA Recalls Artificial Tears in Response to Multi-state Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa*

RECALL: EzriCare Artificial Tears (See FDA link below). Discontinue use of this product for personal and clinical uses immediately.

February 6, 2023

Summary:

The Centers for Disease Control and Prevention (CDC) is investigating an ongoing multi-state outbreak of Verona Integron-mediated Metallo-β-lactamase (VIM) and Guiana-Extended Spectrum-β-lactamase (GES)-producing carbapenem-resistant *Pseudomonas aeruginosa* (VIM-GES-CRPA). There are currently 55 confirmed cases in 12 states, including one case in NM with this rare strain of extensively drug-resistant organism. Isolates have been identified from various clinical cultures including sputum or bronchial wash, cornea, urine, blood, other nonsterile sources, and rectal swabs collected for screening purposes. Specimens have been collected from both inpatient and outpatient healthcare settings. Patients had a variety of presentations including keratitis, endophthalmitis, respiratory infection, urinary tract infection, and sepsis. Patient outcomes include permanent vision loss resulting from cornea infection, hospitalization, and one death due to systemic infection.

Background:

Isolates in this outbreak are sequence type (ST) 1203, harbor *bla*VIM-80 and *bla*GES-9 (a combination not previously observed in the United States) and are closely related based on analysis of whole genome sequencing (WGS) data.

After review of common exposures, most patients involved in this outbreak reported use of artificial tears. Majority of patients who reported the use of artificial tears used EzriCare Artificial Tears; a preservative-free over-the-counter product dispensed in multi-dose bottles manufactured by Global Pharma Healthcare Private Limited. CDC laboratories identified the presence of the VIM-GES-CRPA that matches the outbreak strain in opened bottles of EzriCare Artificial Tears from patients with and without eye infections in two different states. The contamination of the opened bottles of EzriCare Artificial Tears could represent bacterial contamination either during use or during the manufacturing process.

The Food and Drug Administration (FDA) has recalled EzriCare Artificial Tears and Global Pharma has initiated a voluntary consumer recall of the product. The recall was recommended due to the manufacturer's violations of current good manufacturing practices which include the lack of appropriate antimicrobial testing, lack of an adequate preservative in the product formula, and lack of appropriate controls for tamper-evident packaging. The use of this contaminated product can result in eye infections leading to permanent blindness.

Recommendations for Clinicians: Discontinue the use of EzriCare Artificial Tears in healthcare facilities and advise patients who used these artificial tears to monitor signs and symptoms of infection. Clinicians treating patients for keratitis or endophthalmitis should inquire about the use of EzriCare Artificial Tears and consider preforming cultures and antimicrobial susceptibility testing to determine the best course of treatment as isolates associated with this outbreak are extensively drug resistant. Place patients colonized or infected with VIM-GES-CRPA on Contact Precautions if being cared for in an acute care setting or Enhanced Barrier Precautions for residents in skilled nursing facilities. Please report any CRPA eye infections to the New Mexico Department of Health by calling (505)827-0006 or faxing case information to (505)827-0013. Clinical laboratory isolates may also be submitted the Scientific Laboratory Division (SLD) by following lab submission guidelines for CRPA. Questions for the department's healthcare-associated infections program can be directed to Melissa.Judson@doh.nm.gov.

Additional Resources:
www.cdc.gov/hai/outbreaks/CRPA-artificial-tears.html

www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination

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New Mexico Health Alert Network: To register for the NM Health Alert Network, please visit the following site **https://nm.readyop.com/fs/4cjZ/10b2** Please fill out the registration form completely and click Submit at the bottom of the page, to begin receiving Important health alerts, advisories, and updates.

Please Note that our system also utilizes text messaging to notify members of important health information. Due to FCC Regulation changes that are designed to decrease the amount of unwanted spam text messages sent each year to citizens, please save, this phone number (**855) 596-1810** as the **"New Mexico Health Alert Network"** default phone number for your account used for text messages on the mobile device(s) you register with us.