Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost-effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2023-26 **November 2, 2023**

ITEM: **Various Eye Drops: Recall Due to Risk of Infection**

SPECIFIC INCIDENT(S): Certain over-the-counter eye drops are being recalled due to the potential risk of eye infections that could result in partial vision loss or blindness.

GENERAL INFORMATION:

- FDA investigations found unsanitary conditions in several manufacturing facilities and positive bacterial test results from environmental sampling of critical drug production areas within these facilities.
  - Affected products are available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye#eyedrops . *Note: No NDCs were provided by FDA at this time. If you procure product from any of the impacted vendors, please reach out to them directly to obtain additional information.*
- The Harvard Drug Group, LLC doing business as Major® Pharmaceutical and Rugby® Laboratories identified the following products for recall associated with this safety issue: all lots of Polyvinyl Alcohol, 1.4% Lubricating Eye Drops and Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%) supplied by Velocity Pharma, LLC.
  - Affected products were distributed Nationwide starting June 1, 2021, and include:

Brand Name	Product Name	Package Description	NDC
Rugby®	Polyvinyl Alcohol, 1.4% Lubricating Eye Drops	0.5 oz bottle (15 mL)	0536-1325-94
Rugby®	Lubricating Tears Eye Drops (Dextran/Hypromellose, 0.1%/0.3%)	0.5 oz bottle (15 mL)	0536-1282-94

  - The Harvard Drug Group, LLC has received three (3) reports of adverse events related to these products including reports of vision blurriness, vision loss, and burning eyes.
- FDA recommends informing patients who have signs or symptoms of an eye infection after using these products to seek medical care immediately.
- This alert is an extension of the product sequestration actions from NCPS in Safety Record Number SR-46084 available at: VA Alerts & Recalls Live . (Note: Only active users will be able to use the link to view the post.)
- Providers should continue to report any adverse reactions with the use of potentially affected products by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm , or by mail).

ACTIONS: **PROVIDER NOTIFICATION:**

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **Primary Care Providers, Ophthalmologists, Optometrists, and Pharmacy Staff, including contract providers,** etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

Chief of Pharmacy: Within 10 business days of issue (due 11/17/2023):

- Determine whether the affected product(s) was dispensed to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact the patient(s) who may have received the affected product(s) for home use by letter (or other means).
    - A sample letter can be found at: https://dvagov.sharepoint.com/:w:/r/sites/VHAPBM/Formulary/_layouts/15/Doc.aspx?sourcedoc=%7BB49A9262-448D-4BA9-BD67-46D201C8D379%7D&file=ASA%20Recall%20Patient%20Letter%20Template.doc&action=default&mobileredirect=true.
    - This template can be altered according to site-specific needs.
  - Provide patient(s) who have received the affected product with a replacement product and instructions on the following:
    - Advise patients with affected lot number(s) on how to obtain replacement**.** Local sites will need to work with patients to get them what is needed for their care in the most expedient way.
    - The facility is responsible for determining whether or not the potentially impacted product should be continued until new product arrives or if product should be discontinued immediately based on clinical assessment and informing the patient of such.
    - When the correct product is received, patients should begin using the new product and return any unused old product.
- Communicate to PBM/VAMedSAFE that all impacted patients have been contacted via the NCPS Alerts & Recalls System available at: VA Alerts & Recalls Live . (Note: Only active users will be able to use the link.)

SOURCE: FDA; Manufacturer

REFERENCE(S):

1. FDA. Drug Safety and Availability. FDA warns consumers not to purchase or use certain eye drops from several major brands due to risk of eye infection. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye#eyedrops . Accessed 10/31/2023.
2. The Harvard Drug Group LLC Press Release [Data on file, Date 10/31/2023]. The Harvard Drug Group, LLC Issues Voluntary Nationwide Recall of Certain Rugby® Laboratories Brand Eye Drops Supplied by Velocity Pharma, LLC Due to Potential Risk of Eye Infections, written communication, Erich Timmerman, Media Contact, The Harvard Drug Group LLC. October 31, 2023.

ATTACHMENT(S): None.

CONTACT(S): Pharmacy Benefits Management Services (PBM) at patientlevelrecalls@va.gov.