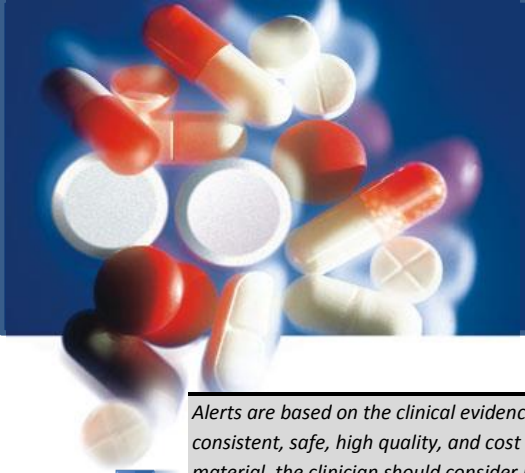

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

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.

PBM-2017-01 **MARCH 6, 2017**

ITEM: SPECIFIC INCIDENT(S):

Alprostadil for Injection (Edex®) – Recall Due to Potential Lack of Sterility Assurance

- Endo Pharmaceuticals Inc. is voluntarily recalling one lot of alprostadil for injection (Edex®) 10 mcg due to the detection of a defect in the crimp caps used in the manufacture of the affected product lot.

GENERAL INFORMATION:

- Alprostadil for injection (Edex®) is a prescription only intracavernous injection indicated for the treatment of male erectile dysfunction.
- The defect detected may compromise container closure integrity, affecting the product's sterility assurance and may lead to serious adverse events such as infections, both localized at the site of injection and systemically.
- To date, Endo has not received adverse event reports related to this recall.
- The recall applies to the 10 mcg strength, packaged in a 2 pack carton, (NDC 52244-010-02), product lot number 207386, Expiration Date: May 2019.
- The affected lot was distributed from December 13, 2016 through February 13, 2017 to wholesale distributors and retail pharmacies throughout the United States.
- This recall is an extension of the product sequestration actions in **Product Recall Office Log # 11698** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of alprostadil for injection (Edex®) 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/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **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, urology staff, 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.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

- **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 03/17/2017):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template.doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to take the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
  - Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S): FDA Recalls, Market Withdrawals, & Safety Alerts. Endo Pharmaceuticals Inc. Issues Voluntary Nationwide Recall for One Lot of Edex® (alprostadil for injection) 10 mcg 2 Pack Carton Due to Potential Lack of Sterility Assurance. https://www.fda.gov/Safety/Recalls/ucm543470.htm . (Accessed 3/1/2017).

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.