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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-2017-11 **AUGUST 23, 2017**

ITEM: **Lorazepam Oral Concentrate, USP 2mg/mL Recall Due to Misprinted Dosing Droppers Supplied with the Product**

SPECIFIC INCIDENT(S):

Amneal Pharmaceuticals LLC is voluntarily recalling 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, due to a defect in the dropper markings that may result in dispensing either less than, or more than, the prescribed dose.

GENERAL INFORMATION:

- Lorazepam is indicated for the management of anxiety disorders for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.
- It has been reported that the dropper is printed with the dose markings in reverse number order, has no dose markings, or has dose markings that are shifted.
- There is no safety issue with the bottled product itself.
- A potential harm may arise if a patient receives less than the prescribed dose and experiences suboptimal symptom control. In addition, potential serious adverse events may be likely if more than prescribed dose is administered.
- To date, no adverse events related to these dropper defects have been reported to the manufacturer.
- The affected Lorazepam Oral Concentrate, USP 2mg/mL product can be identified by the following NDC 65162-687-84, with specific lots including:

Lot Number	Expiration Date
06876016A	08/2018
06876017A	08/2018
06876018A	08/2018
06876019A	09/2018
06876020A	09/2018
06876021A	09/2018
06876022A	09/2018
06876023A	11/2018
06876024A	12/2018
06876025A	12/2018
06877001A	02/2019
06877002A	02/2019
06877003A	03/2019

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- Per manufacturer, Amneal began shipping the subject lots on November 3, 2016.
- This is an extension of the product sequestration actions in **Product Recall Office Log # 12242** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of affected Lorazepam Oral Concentrate, USP 2mg/mL 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, mental health specialists, 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 09/07/2017):
  - 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.

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- 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. Amneal Pharmaceuticals Issues Voluntary Nationwide Recall of Lorazepam Oral Concentrate, USP 2mg/mL, Due to Misprinted Dosing Droppers Supplied with the Product. https://www.fda.gov/safety/recalls/ucm571787.htm . Accessed August 14, 2017.

ATTACHMENT(S): None.

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