Amneal Pharmaceuticals Issues Voluntary Nationwide Recall of Lorazepam Oral Concentrate, USP 2mg/mL, Due to Misprinted Dosing Droppers Supplied with the Product

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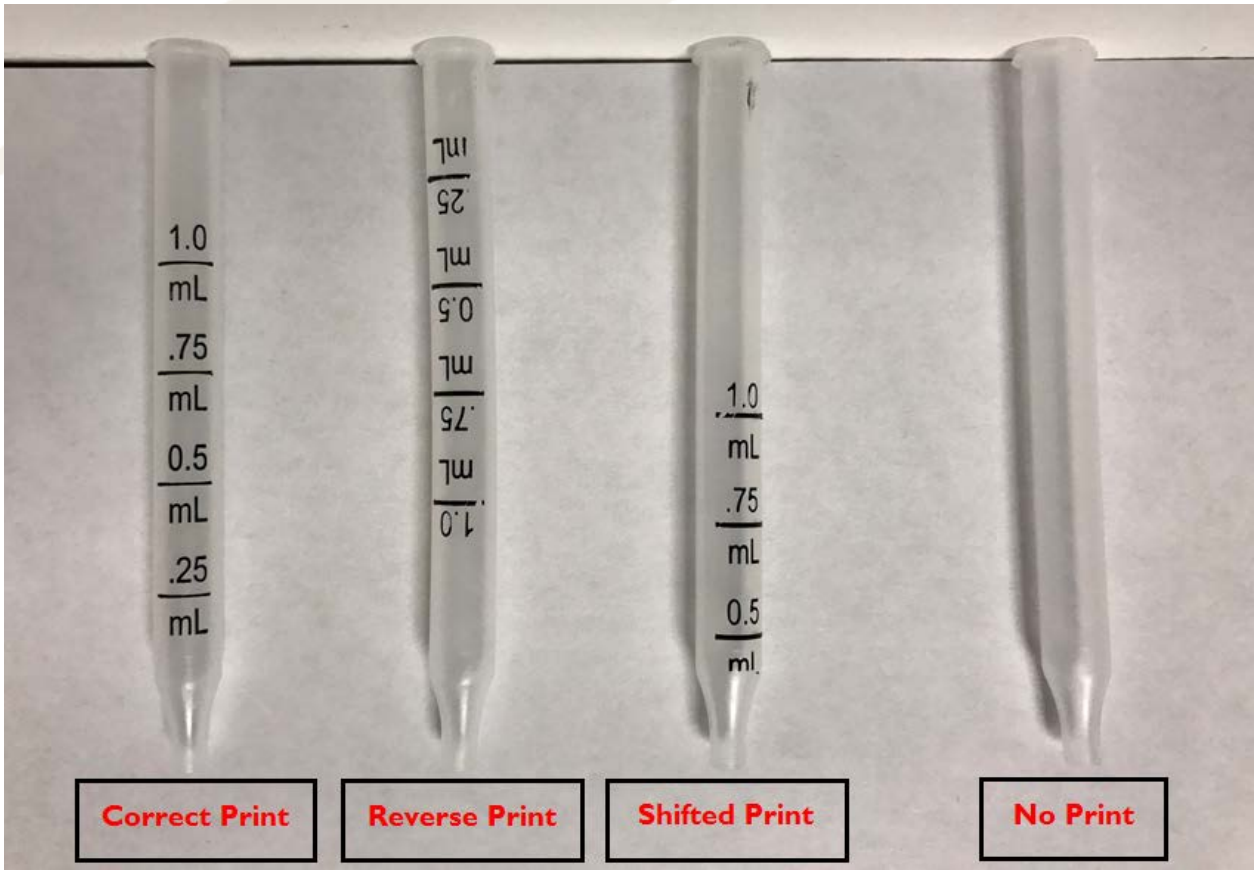
FOR IMMEDIATE RELEASE – Bridgewater, N.J., August 19, 2017 – Amneal Pharmaceuticals LLC is voluntarily recalling 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, to the Consumer level due to a defect in the dropper markings. The Lorazepam Oral Concentrate, USP 2mg/mL, product is packaged with a dosing dropper, supplied to Amneal by a third party. In a few instances, the dropper is printed with the dose markings in reverse number order, has no dose markings or has dose markings that are shifted. Amneal learned about the issue from a Consumer's report. To date no adverse events related to these dropper defects have been reported to Amneal. The below picture shows examples of a dropper with the correct print, along with examples of droppers with the defects.



Risk Statement: There is a significant likelihood that the dropper marking errors will result in dispensing either less than, or more than, the prescribed dose. There is a significant probability of a serious health consequence if more than the prescribed dose is dispensed and potential serious adverse events include – drowsiness causing trauma; increased anxiety; increased accidental injury to self or others (e.g., hip fracture, motor vehicle accident); which in the most serious circumstances could result in permanent decreased function or death.

The product 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 is packaged in an individual carton, identified with the code: NDC 65162-687-84, which contains a 30mL amber glass bottle of liquid produced by Amneal, a package insert with patient information, and a plastic dropper sealed in a clear plastic bag. The affected Lorazepam Oral Concentrate, USP 2mg/mL, lots are the following:

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

The product can be identified by the lot number printed on the bottom-right side of the blue and white label, with the Amneal logo, on the amber bottle supplied with the dropper, in a blue and white carton, with the Amneal logo. The Lorazepam Oral Concentrate, USP 2mg/mL was distributed nationwide to wholesalers.

Amneal Pharmaceuticals has notified its wholesale customers by a Recall Letter to return all recalled lots. Amneal is notifying pharmacies by providing a Recall Letter and a supply of replacement droppers to all pharmacies that may have received any of the recalled lots. There is no safety issue with the bottled product itself. To avoid any interruption in supply or access to the medication by the patient, pharmacies are instructed to immediately discard the dropper included with the recalled lots and replace it with the dropper included with the Recall Letter. Amneal also is providing the pharmacist with a sticker which the pharmacist is required to place on the box to alert the patient and other pharmacists that the dropper has been replaced. Pharmacists are instructed to notify all Consumers impacted by the recall of the potential defect and the need to exchange a defective dropper. Consumers are instructed to discontinue use of any defective dropper and return it to the place of purchase for a replacement. If Consumers are unsure whether their droppers are defective they are encouraged to confirm with their dispensing pharmacy.

AUGUST 19, 2017 UPDATE:

Customers also may call Amneal directly at 1 (877) 835-5472 to request a replacement dropper.

Consumers with questions regarding this recall can contact Amneal Pharmaceuticals at 631.633-2142 or amnealreg@amneal.com on Monday through Friday from 9AM through 5PM Eastern Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit report **Online: www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax:** Download **form www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/Med-Watch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Amneal:

Amneal Pharmaceuticals LLC, a privately-held, global, company headquartered in Bridgewater, New Jersey, was founded in 2002 and is one of the largest and fastest growing generic pharmaceutical manufacturers in the United States.

Click here to view full prescribing information for Lorazepam Oral Concentrate.