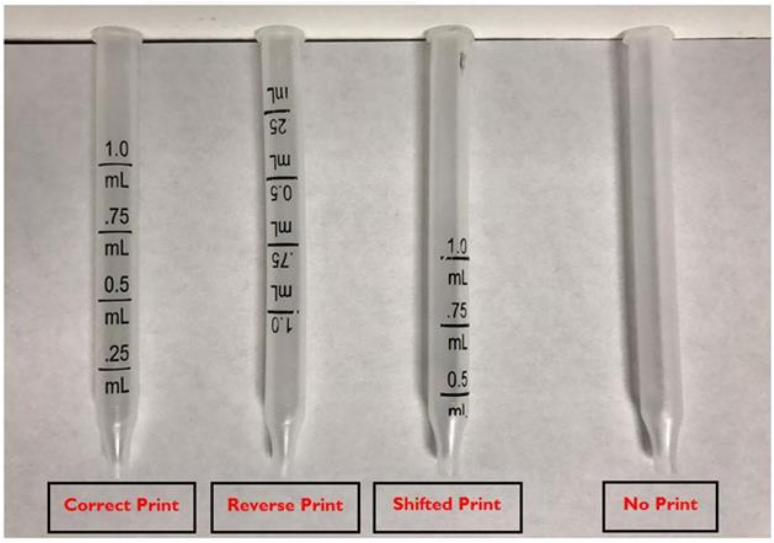
Voluntary Recall: Lorazepam Oral Concentrate, USP 2mg/ml by Amneal Pharmaceuticals - Misprinted Dosing Droppers

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on August 16, 2017 the FDA issued a statement notifying the voluntary retirement of 13 lots of Lorazepam Oral Concentrate, USP 2mg/mL, to the Consumer level due to a defect in the dropper markings. In 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. (See figure 1.) There is a significant likelihood that the dropper marking errors will result in dispensing either less than, or more than, the prescribed dose. The affected lots are detailed in the following table.

Product	Affected Lot	Expiration Date
Lorazepam Oral Concentrate, USP 2mg/mL NDC: 65162-687-84	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

Figure 1. Misprinted dosing droppers



The Pharmacy must:

1. Immediately discard the dropper and replace with the new received by Amneal Pharmaceuticals through a Recall Letter
2. For questions regarding this recall can contact Amneal Pharmaceuticals

For additional information visit:

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm571796.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Department of Clinical Pharmacy