

### Amneal – Recall of lorazepam oral concentrate

- On August 14, 2017, [Amneal announced](#) a consumer-level recall of thirteen lots of [lorazepam](#) oral concentrate 2 mg/mL due to a defect in the dropper markings. Lorazepam oral concentrate is packaged with a dosing dropper, supplied to Amneal by a third party.
- In a few instances, the dropper was printed with the dose markings in reverse number order, had no dose markings, or had dose markings that were shifted. Amneal learned about the issue from a consumer's report. There is no safety issue with the drug itself.

Product Description	NDC #	Lot # (expiration date)
Lorazepam oral concentrate, 2mg/mL, 30 mL bottle	65162-687-84	06876016A (8/2018); 06876017A (8/2018); 06876018A (8/2018); 06876019A (9/2018); 06876020A (9/2018); 06876021A (9/2018); 06876022A (9/2018); 06876023A (11/2018); 06876024A (12/2018); 06876025A (12/2018); 06877001A (2/2019); 06877002A (2/2019); 06877003A (3/2019)

- Lorazepam is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.
- 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 (eg, hip fracture, motor vehicle accident); which in the most serious circumstances could result in permanent decreased function or death.
- To date, no adverse events related to these dropper defects have been reported to Amneal.
- The recalled 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.
- Amneal has notified its wholesale customers by 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.
- 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 a new dropper provided by Amneal. 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.

- Patients are instructed to discontinue use of any defective dropper and return it to their pharmacy for a replacement. If patients are unsure whether their droppers are defective, they are encouraged to confirm with their dispensing pharmacy.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using lorazepam oral concentrate.
- Contact Amneal at **1-631-952-0214** for any questions regarding this recall.



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