

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Amneal Pharmaceuticals LLC is initiating this recall of one lot of **Magnesium Sulfate in Water for Injection, USP 4 g/100mL (NDC 70121-1720-3)** due to a potential for a Magnesium Sulfate in Water for Injection foil pouch to contain an IV bag of Tranexamic Acid in 0.7% Sodium Chloride Injection, 10 mg/mL.

Magnesium sulfate in water for injection is indicated for the prevention and control of seizures in preeclampsia and eclampsia, respectively.

Tranexamic acid in 0.7% sodium chloride injection is indicated in patients with hemophilia for short-term use to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

A substitution between **Magnesium Sulfate in Water for Injection** and **Tranexamic Acid in 0.7% Sodium Chloride Injection** would be clinically consequential if administered, as these products differ significantly in therapeutic purpose, mechanism of action, indication, and toxicity. The likelihood of such a mix-up reaching a patient is considered low as hospital medication-administration controls provide multiple safety checks prior to administration. Additionally, each Tranexamic Acid IV bag is clearly labeled with the product name and includes a readable bar code, making incorrect identification readily detectable. The inspection of approximately 74% of the batch resulted in no similar issues except for one reported event. However, in an abundance of caution and to uphold the highest standards of patient safety, Amneal is recalling the impacted lot.

This recall is being carried out to the Hospital Level.

PRODUCT: Magnesium Sulfate in Water for Injection, USP 4 g/100mL

NDCNUMBER: 70121-1720-3

LOT NUMBER: AH250162

EXPIRATION DATE: 08/2027

SHIP DATES: 12/29/2025 - 2/27/2026