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Amneal issues a nationwide voluntary recall of vancomycin hydrochloride for oral solution due to the potential for some bottles to be super potent

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About this recall:

Amneal is voluntarily recalling four lots of vancomycin hydrochloride for oral solution, USP, 250 mg/5 mL, packaged in pack sizes of 80 mL, 150 mL or 300 mL, to the consumer level. Some bottles may have been overfilled, which can result in an overpotent dosing regimen. The recommended maximum daily dose is up to 2 gm/day, and patients prescribed a dosing regimen of 500 mg/10 mL would exceed this daily allowance, which may be harmful to patients with kidney insufficiency. The following NDCs and lot numbers are being recalled.

| NDC | Lot | Expiration date | Pack size |
|---------------|-----------|-----------------|-----------|
| 69238-2261-03 | 22613003A | 09/2025 | 80 mL |
| 69238-2261-07 | 22613004A | 09/2025 | 150 mL |
| 69238-2261-07 | 22613005A | 09/2025 | 150 mL |
| 69238-2261-05 | 22613005B | 09/2025 | 300 mL |

Vancomycin hydrochloride for oral solution is administered for treatment of inflammation of the intestines caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis (inflammation of the inner lining of the large intestine) caused by *Clostridioides difficile* (*C. difficile*).

What this means to you:

Adult patients who are prescribed the maximum daily dose of up to 2 grams per day of vancomycin hydrochloride for oral solution, 250 mg/5 mL, may receive up to 4 grams of oral vancomycin per day due to the overfilled bottle. Some patients with inflammatory disorders of the intestines also may have substantial absorption of the vancomycin. These patients may be at risk for adverse effects associated with higher doses of vancomycin. Worsening kidney function could be associated with electrolyte abnormalities such as high potassium leading to cardiac arrest.

Consumers who have vancomycin hydrochloride for oral solution, USP, 250 mg/mL, should examine the bottle, stop using the product if the NDC and lot number is listed on the recall, and contact Amneal via phone or email for recall information and for product return instructions. For further information and instructions on product return, consumers may call Amneal at **833.582.0812**, Monday–Friday, 8 a.m. to 5 p.m. Eastern Standard Time (EST), or email **Vancomycin_Recall@Amneal.com**. Consumers should contact their health care provider if they have experienced any problems that may be related to taking or using this drug product.