

Amneal – Recall of vancomycin oral solution

- On March 27, 2024, [Amneal announced](#) a consumer-level recall of four lots of [vancomycin](#) oral solution because some bottles may have been overfilled which can result in a super potent dosing regimen.
- The recommended maximum daily dose allowance for this product 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 renal insufficiency. The error occurred during the manual bottle filling stage of manufacturing.
- This recalled lot was distributed nationwide to pharmacies from November 9, 2023 and February 20, 2024.

Product Description	NDC number	Lot number (Exp Date)
Vancomycin for oral solution, 250 mg/5mL	69238-2261-3	22613003A (9/2025)
	69238-2261-7	22613004A (9/2025); 22613005A (9/2025)
	69238-2261-5	22613005B (9/2025)

- Vancomycin oral solution is administered orally for treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by *C. difficile*.
- Adults who are prescribed the maximum daily dose of up to 2 grams per day of vancomycin oral solution, 250 mg/5 mL, may receive up to 4 grams of oral vancomycin per day because of the overfilled bottle.
- Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for the development of adverse reactions associated with higher doses of vancomycin oral solution. Worsening renal function could be associated with electrolyte abnormalities such as high potassium leading to cardiac arrest.
- To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall.
- Anyone with the affected product on hand should discontinue use, stop distribution and quarantine product immediately. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.
- Consumers may contact Amneal by phone at **1-833-582-0812** or by email at Vancomycin_Recall@amneal.com for more information.