Magellan Medicaid Administration

Amneal Issues a Nationwide Voluntary Recall of Vancomycin Hydrochloride for Oral Solution Due to the Potential for Some Bottles to be Super Potent

Date: 03/27/2024

About this recall:
Amneal is voluntarily recalling 4 lots of Vancomycin Hydrochloride for Oral Solution, USP, 250 mg/5 mL packaged in 80 mL, 150 mL, or 300 mL pack sizes, to the consumer level. Some bottles may have been overfilled which can result in an over potent 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 Number	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 telephone or email for recall information and for product return instructions. Consumers may call Amneal at 1-833-582-0812 Monday through Friday, 8:00 am to 5:00 pm, EST, or email Vancomycin_Recall@amneal.com for further information and instructions on the product return. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-nationwide-voluntary-recall-vancomycin-hydrochloride-oral-solution

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.

