

Government of the Republic of Trinidad and Tobago

Ministry of Health

CORPORATE COMMUNICATIONS UNIT

#4-6 Queen's Park East, Port of Spain 101002

MEDIA RELEASE

April 9, 2024

Voluntary Recall Notice of Vancomycin Hydrochloride for Oral Solution USP, 250mg/5mL

Port of Spain, April 9, 2024: The Ministry of Health (MoH), via its Drug Inspectorate, advises of a voluntary recall notice of four (4) lots of Vancomycin Hydrochloride for Oral Solution, USP, 250 mg/5mL packaged in 80 mL, 150 mL, or 300 mL pack sizes. The recall was issued by Amneal Pharmaceuticals, LLC due to the potential overfilling of bottles.

Vancomycin Hydrochloride for Oral Solution, USP is administered for the treatment of enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by C. difficile.

Due to the potential overfilling of these bottles, patients who are prescribed the maximum daily dose of up to 2 grams per day of Vancomycin Hydrochloride for oral solution, USP 250 mg/5mL, may receive up to 4 grams of oral vancomycin per day. Patients with compromised intestinal/stomach and renal function, may be at risk for electrolyte abnormalities such as high potassium which may lead to cardiac arrest.

While the recalled products are not registered for sale in Trinidad and Tobago, out of an abundance of caution, the Ministry advises persons who may be in possession of these recalled products to discontinue use immediately and to return the product to the place of purchase where possible.

Additional Information can be obtained by contacting the Office of the Drug Inspectorate via email at drug.inspectoratett@gmail.com or phone at 217-4664 ext. 13404.







The Ministry of Health will continue to monitor the situation and advise the population as necessary.

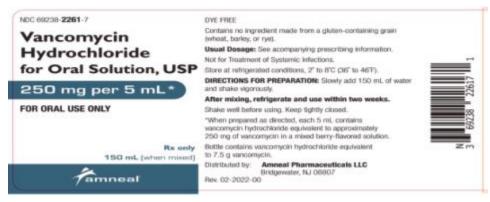




RECALLED PRODUCTS

| NDC No. | Lot | Expiration Date | Pack Size |
|--------------|-----------|-----------------|-----------|
| 69238-2261-3 | 22613003A | 09/2025 | 80 mL |
| 69238-2261-7 | 22613004A | 09/2025 | 150 mL |
| 69238-2261-7 | 22613005A | 09/2025 | 150 mL |
| 69238-2261-5 | 22613005B | 09/2025 | 300 mL |







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