



Government of the Republic of Trinidad and Tobago

Ministry of Health

CORPORATE COMMUNICATIONS UNIT

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

M E D I A R E L E A S E

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.



1(868) 217-4664
Ext. 16201-16212



www.health.gov.tt



corporatecommunications@health.gov.tt

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



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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

NDC 69238-2261-3

Vancomycin Hydrochloride for Oral Solution, USP

250 mg per 5 mL*

FOR ORAL USE ONLY

Rx only
80 mL (when mixed)



DYE FREE
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

Usual Dosage: See accompanying prescribing information. Not for Treatment of Systemic Infections. Store at refrigerated conditions, 2° to 8°C (36° to 46°F).

DIRECTIONS FOR PREPARATION: Slowly add 80 mL of water and shake vigorously.

After mixing, refrigerate and use within two weeks. Shake well before using. Keep tightly closed.

*When prepared as directed, each 5 mL contains vancomycin hydrochloride equivalent to approximately 250 mg of vancomycin in a mixed berry-flavored solution.

Bottle contains vancomycin hydrochloride equivalent to 4 g vancomycin.

Distributed by: **Anneal Pharmaceuticals LLC**
Bridgewater, NJ 08807
Rev. 02-2022-00


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NDC 69238-2261-7

Vancomycin Hydrochloride for Oral Solution, USP

250 mg per 5 mL*

FOR ORAL USE ONLY

Rx only
150 mL (when mixed)



DYE FREE
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

Usual Dosage: See accompanying prescribing information. Not for Treatment of Systemic Infections. Store at refrigerated conditions, 2° to 8°C (36° to 46°F).

DIRECTIONS FOR PREPARATION: Slowly add 150 mL of water and shake vigorously.

After mixing, refrigerate and use within two weeks. Shake well before using. Keep tightly closed.

*When prepared as directed, each 5 mL contains vancomycin hydrochloride equivalent to approximately 250 mg of vancomycin in a mixed berry-flavored solution.

Bottle contains vancomycin hydrochloride equivalent to 7.5 g vancomycin.

Distributed by: **Anneal Pharmaceuticals LLC**
Bridgewater, NJ 08807
Rev. 02-2022-00


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NDC 69238-2261-5

Vancomycin Hydrochloride for Oral Solution, USP

250 mg per 5 mL*

FOR ORAL USE ONLY

Rx only
300 mL (when mixed)



DYE FREE
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

Usual Dosage: See accompanying prescribing information. Not for Treatment of Systemic Infections. Store at refrigerated conditions, 2° to 8°C (36° to 46°F).


DIRECTIONS FOR PREPARATION: Slowly add 300 mL of water and shake vigorously.

After mixing, refrigerate and use within two weeks. Shake well before using. Keep tightly closed.

*When prepared as directed, each 5 mL contains vancomycin hydrochloride equivalent to approximately 250 mg of vancomycin in a mixed berry-flavored solution.

Bottle contains vancomycin hydrochloride equivalent to 15 g vancomycin.

Distributed by: **Anneal Pharmaceuticals LLC**
Bridgewater, NJ 08807
Rev. 02-2022-00


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