



## Azurity – Recall of Firvanq® (vancomycin for oral solution)

- On September 8, 2021 [Azurity announced](#) a voluntary, patient-level recall of one lot of [Firvanq \(vancomycin for oral solution\)](#) 50 mg/mL kit because some products in the affected lot have been found to incorrectly contain a First Omeprazole (FIRST-PPI) diluent instead of the Firvanq diluent bottle.
  - Firvanq oral solution that is not being recalled is available for patients to use.

Product Description	NDC#	Lot# (Expiration Date)
Firvanq (vancomycin for oral solution) 50 mg/mL kit; each kit contains vancomycin powder for oral solution, equivalent to 7.5 g vancomycin and grape flavored diluent	65628-206-05	21035 (7/31/2022)

- Firvanq is indicated for the treatment of *Clostridium difficile*-associated diarrhea in adults and pediatric patients < 18 years of age and for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) in adults and pediatric patients < 18 years of age.
- Vancomycin may not be completely solubilized in the FIRST-PPI diluent which could lead to doses above or below those recommended in the label.
  - There is reasonable probability that the administration of inappropriate doses of oral vancomycin may lead to persistent diarrhea associated with dehydration and electrolyte abnormalities, recurrence of *Clostridium difficile* infection, its progression to severe colitis, colon perforation requiring colectomy, and potentially death.
  - The elderly and immunocompromised patients are vulnerable to the complications of *C. difficile* infection.
  - To date, Azurity has not received any reports of adverse events related to this recall.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled Firvanq.
- Anyone with an existing inventory of the recalled product should stop use, distribution, quarantine the product immediately, and return to the place of purchase.
- Contact Koral Couch, Senior Manager of Azurity Customer Service by phone: **1-781-935-8141 (ext. 119)**; fax: **1-781-935-8395** or email: [kcouch@azurity.com](mailto:kcouch@azurity.com) for more information about this recall.



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