

Firvanq™ (vancomycin) – New drug approval

- On January 29, 2018, [CutisPharma announced](#) the FDA approval of [Firvanq \(vancomycin\)](#) powder for oral solution, in adults and pediatric patients less than 18 years of age for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) and enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).
 - Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.
 - Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.
- Vancomycin is also available generically as [capsules](#) and [injectable solution](#).
 - The capsules have the same indication as the oral solution.
 - The injectable solution is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (β -lactam-resistant) staphylococci. Consult vancomycin's injectable solution label for more detailed information about indications.
 - The injectable solution may also be used orally to treat the same indications as the capsules and oral solution.
- The efficacy of vancomycin was demonstrated in two trials of 266 adult patients with CDAD. Patients received vancomycin 125 mg orally four times daily for 10 days. Efficacy was assessed by using clinical success, defined as diarrhea resolution and the absence of severe abdominal discomfort due to CDAD, on day 10.
 - In trial 1, clinical success was seen in 81.3% (95% CI: 74.4, 88.3) of patients treated with vancomycin.
 - In trial 2, clinical success was seen in 80.8% (95% CI: 73.5, 88.1) of patients treated with vancomycin.
 - In addition, the median time to resolution of diarrhea was 5 days and 4 days in trial 1 and trial 2, respectively.
- Warnings and precautions of Firvanq include oral use only, potential for systemic absorption, nephrotoxicity, ototoxicity, potential for microbial overgrowth, development of drug-resistant bacteria, and hemorrhagic occlusive retinal vasculitis.
- The most common adverse reactions ($\geq 10\%$) associated with Firvanq use were nausea (17%), abdominal pain (15%), and hypokalemia (13%).
- Firvanq must be reconstituted by a healthcare provider prior to administration. The recommended dosage of Firvanq varies by indication as follows:
 - For the treatment of CDAD in adults, the recommended dose is 125 mg administered orally 4 times daily for 10 days.
 - For the treatment of staphylococcal enterocolitis in adults, the recommended dose is a total daily dosage of 500 mg to 2 g administered orally in 3 or 4 divided doses for 7 to 10 days.
 - For the treatment CDAD or staphylococcal enterocolitis in pediatric patients, the usual dose is 40 mg/kg in 3 or 4 divided doses for 7 to 10 days. The total daily dosage should not exceed 2 g.

- Firvanq will replace CutisPharma's FIRST[®]-Vancomycin Unit-of-Use Compounding Kit, which has been available to pharmacists to compound vancomycin oral liquid therapy.
- CutisPharma plans on launching Firvanq on April 2, 2018. Firvanq will be available as a kit containing vancomycin 3.75 g, 7.5 g, 10.5 g, and 15 g powders for oral solution with a grape-flavored diluent. When reconstituted, the Firvanq strengths will be 25 mg/mL and 50 mg/mL.



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