

Aemcolo™ (rifamycin) – New drug approval

- On November 16, 2018, the [FDA announced](#) the approval [Cosmo Pharmaceuticals' Aemcolo \(rifamycin\)](#), for the treatment of travelers' diarrhea (TD) caused by non-invasive strains of *Escherichia coli* (*E. coli*) in adults.
 - Aemcolo is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of *E. coli*.
- TD is the most common travel-related illness, affecting an estimated 10 to 40% of travelers worldwide each year. TD is defined by having three or more unformed stools in 24 hours, in a person who is traveling. It is caused by a variety of pathogens, but most commonly bacteria found in food and water. The highest-risk destinations are in most of Asia as well as the Middle East, Africa, Mexico, and Central and South America.
- Aemcolo belongs to the ansamycin class of antibacterial drugs and acts by inhibiting the beta-subunit of the bacterial DNA-dependent RNA polymerase. This results in inhibition of bacterial synthesis and consequently growth of bacteria.
 - Aemcolo is the first antibiotic engineered with Cosmo Pharmaceuticals' Multi Matrix Technology which allows for the colonic release of active ingredient.
- The efficacy of Aemcolo was primarily evaluated in a double-blind, placebo-controlled study in 264 adults with TD. A second active-controlled study provided supportive evidence for the efficacy of Aemcolo. The clinical efficacy of Aemcolo was assessed using an endpoint of time to last unformed (watery or soft) stool (TLUS) before achieving clinical cure. The endpoint of clinical cure was defined as two or fewer soft stools and minimal enteric symptoms at the beginning of a 24-hour period or no unformed stools at the beginning of a 48-hour period.
 - In study 1, Aemcolo significantly reduced the TLUS vs. placebo (46.0 hours vs. 68.0 hours, respectively; $p = 0.0008$). Clinical cure was achieved in 81.4% and 56.9% of Aemcolo- and placebo-treated patients ($p = 0.0001$).
 - The results of study 2 supported the results presented for study 1.
- Warnings and precautions of Aemcolo include diarrhea complicated by fever and/or bloody stool, *Clostridium difficile*-associated diarrhea, and development of drug-resistance bacteria.
- The most common adverse reactions (> 2%) with Aemcolo use were headache and constipation.
- The recommended dose of Aemcolo is 388 mg (two tablets) orally twice daily (in the morning and evening), with or without food, for three days.
 - Each dose should be taken with a glass of liquid (6 to 8 ounces).
 - Aemcolo should not be taken concomitantly with alcohol.

- Cosmo Pharmaceuticals plans to launch Aemcolo in the first quarter of 2019. Aemcolo will be available as a 194 mg delayed-release tablet.



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