

## FDA approves drug for treatment of travelers' diarrhea

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(HealthDay)—The U.S. Food and Drug Administration on Friday



announced it has approved Aemcolo (rifamycin), an antibacterial drug indicated for treating adult patients with travelers' diarrhea caused by noninvasive strains of *Escherichia coli* (*E. coli*) without fever or blood in the stool.

Travelers' diarrhea affects an estimated 10 to 40 percent of travelers worldwide each year, according to an FDA press release. The highest-risk destinations are most of Asia, the Middle East, Africa, Mexico, and Central and South America.

The FDA says the drug's efficacy was shown in a randomized, placebo-controlled clinical trial involving 264 adults with travelers' diarrhea in Guatemala and Mexico. Data showed significantly reduced symptoms of travelers' diarrhea with Aemcolo compared with placebo. Two controlled clinical trials involving 619 adults with travelers' diarrhea who took Aemcolo orally for a period of three or four days showed the drug is safe, with the most common adverse reactions being headache and constipation.

Aemcolo is not effective in patients with diarrhea complicated by fever and/or bloody stool or in those with diarrhea due to pathogens other than noninvasive strains of *E. coli*. The FDA does not recommend using Aemcolo for these patients. The agency also says not to use Aemcolo in patients with a known hypersensitivity to rifamycin, any of the other rifamycin class antimicrobial agents (e.g., rifaximin), or any of the components in Aemcolo.

**More information:** More Information

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