Home > FDA approves new drug to treat travelers' diarrhea

Generic Name:
Rifamycin

Trade Name:
Aemcolo

Company:
Cosmo Technologies

Notes:

On November 16, FDA approved rifamycin, an antibacterial drug indicated for the treatment of adult patients with travelers' diarrhea caused by noninvasive strains of Escherichia coli, not complicated by fever or blood in the stool.

Travelers' diarrhea is the most common travel-related illness, affecting an estimated 10% to 40% percent of travelers worldwide each year. Travelers' diarrhea 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.

Efficacy of rifamycin was demonstrated in a randomized, placebo-controlled clinical trial in 264 adults with travelers' diarrhea in Guatemala and Mexico. It showed that rifamycin significantly reduced symptoms of travelers' diarrhea compared with placebo.

Its safety, taken orally over 3 or 4 days, was evaluated in 619 adults with travelers' diarrhea in two controlled clinical trials. The most common adverse reactions were headache and constipation.

Rifamycin was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool or diarrhea caused by pathogens other than noninvasive strains of E. coli and is not recommended for use in such patients.

It also should not be used in patients with a known hypersensitivity to rifamycin, any of the other rifamycin-class antimicrobial agents (e.g. rifaximin), or any of the drug's components.

FDA granted rifamycin a Qualified Infectious Disease Product (QIDP) designation, which is given to antibacterial and antifungal drug products that treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act.

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