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In Vitro Activity and Single-Step Mutational Analysis of Rifamycin SV Tested Against Enteropathogens Associated With Travelers' Diarrhea and Clostridium difficile.

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### **Abstract**

Rifamycin SV is a broad-spectrum, poorly-absorbed antimicrobial agent that, when coupled with MMX® technology, is being targeted for the oral treatment of travelers' diarrhea (TD) and Clostridium difficile-associated disease (CDAD). Rifamycin SV was tested for activity against 911 TD-associated enteropathogens and 30 C. difficile isolates collected from several global surveillance studies. Rifamycin SV demonstrated similar antimicrobial activity among the Enterobacteriaceae, with MIC<sub>50</sub> values ranging from 32 to 128 µg/ml for all but one strain (an enterotoxigenic Eschericia coli at >512 µg/ml). Among non-Enterobacteriaceae strains, MIC<sub>50</sub> values ranged from 2 to 8 µg/ml, with the exception of Campylobacter spp., where all strains had MIC values of >512 µg/ml. Rifamycin SV also demonstrated excellent activity (MIC<sub>50</sub>, ≤0.03 µg/ml) against most C. difficile (including one hypervirulent NAP1 strain), even superior to the potency observed for vancomycin, metronidazole and rifaximin. In mutational passaging studies, rifamycin SV induced stable resistance and showed mutation frequency in E. coli similar to that of rifampin. This study presents the potency of rifamycin SV for enteropathogens commonly recovered from patients with TD and CDAD. Additional in vitro and in vivo studies appear necessary to determine the utility of rifamycin SV as an oral agent for the prevention and treatment of TD and CDAD.

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