Rifaximin for the Reduction in Risk of Overt HE Recurrence

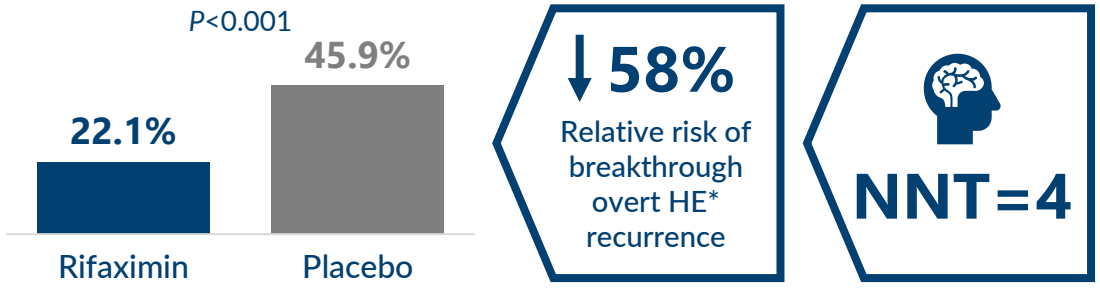
Bass NM, et al. Rifaximin treatment in hepatic encephalopathy. *N Engl J Med.* 2010;362(12):1071-1081.

Phase 3, double-blind, placebo-controlled trial of adults with cirrhosis and history of overt HE

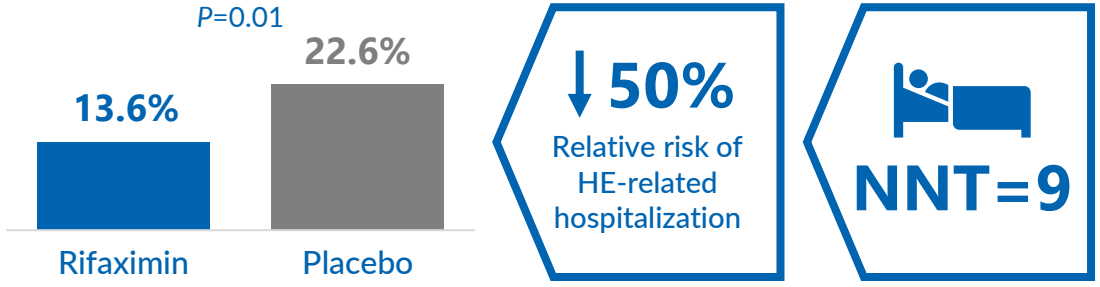
Inclusion criteria: ≥2 overt HE* episodes during previous 6 months (currently in remission); MELD score ≤25	ITT	Male	MELD score 11-18	Age, mean (SD)	Concomitant lactulose
Rifaximin 550 mg bid	n=140	53.6%	67.1%	55.5 (9.6) y	91.4%
Placebo	n=159	67.3%	60.4%	56.8 (9.2) y	91.2%

Rifaximin 550 mg bid vs placebo during 6-month treatment

Breakthrough overt HE episode (primary endpoint)



HE-related hospitalization (key secondary endpoint)



Most commonly reported AEs†

	Rifaximin (n=140)	Placebo (n=159)
Nausea	14.3%	13.2%
Diarrhea	10.7%	13.2%
Fatigue	12.1%	11.3%
Peripheral edema	15.0%	8.2%
Ascites	11.4%	9.4%
Dizziness	12.9%	8.2%
Headache	10.0%	10.7%

*Conn score ≥2 (remission defined as Conn score 0 or 1). †≥10.0% of patients in rifaximin group, regardless of causality. AE = adverse event; bid = twice daily; HE = hepatic encephalopathy; ITT = intention-to-treat; MELD = Model for End-Stage Liver Disease; NNT = number needed to treat to prevent one event (with rifaximin treatment [91.4% of patients were taking concomitant lactulose at baseline]).

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