Two-Week Course of Rifaximin for Patients With IBS-D*

Pimentel M, et al. N Engl J Med. 2011;364(1):22-32.

Pooled analysis of 2 identically designed, phase 3, double-blind RCTs

Inclusion criteria: adults with IBS (Rome II)* with average daily score of 2-4.5† for abdominal pain/discomfort and for bloating, and score of ≥3.5‡ for stool consistency

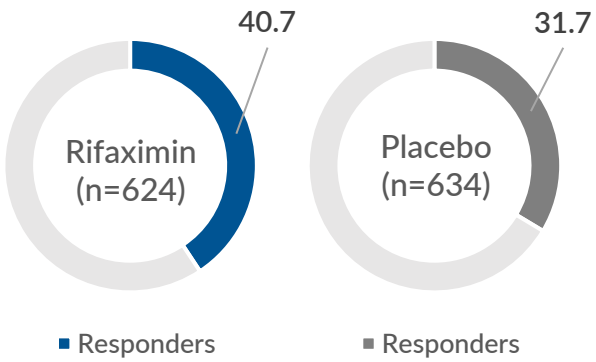
2-wk course; 10-wk follow-up

	Patients	Female	Age <65 y
Rifaximin 550 mg tid	n=624	74.0%	89.7%
Placebo	n=634	70.5%	88.2%

Mean baseline symptom scores	Rifaximin	Placebo
Global IBS symptoms†	3.4	3.4
Abdominal pain/discomfort†	3.3	3.2-3.3
Bloating†	3.2-3.3	3.3
Stool consistency‡	3.9	3.9

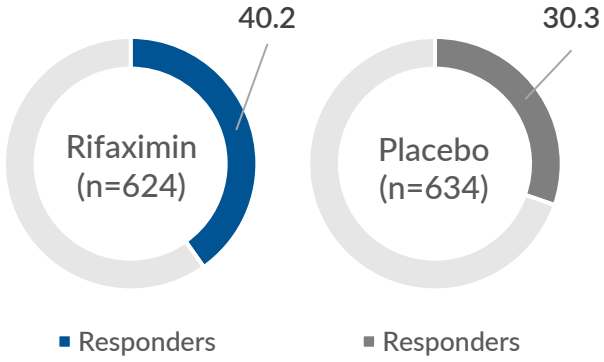
Adequate relief of global IBS symptoms (primary endpoint)§

P<0.001 vs placebo



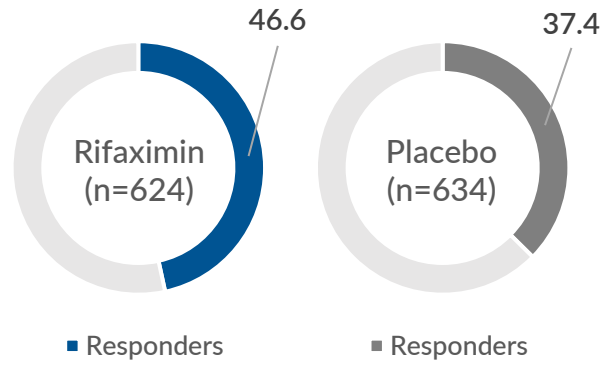
Adequate relief of bloating (key secondary endpoint)¶

P<0.001 vs placebo



Abdominal pain/discomfort and stool consistency composite response (exploratory endpoint)#

P<0.001 vs placebo



AE Profile

	Rifaximin (n=624	Placebo (n=634)
Serious AEs	1.6%	2.4%
Most common AEs**		
Headache	6.1%	6.6%
URTI	5.6%	6.2%
Abdominal pain	4.6%	5.5%
Nasopharyngitis	3.0%	5.4%

*All patients in 2 trials had IBS-D (Schoenfeld P, et al. *Aliment Pharmacol Ther.* 2014;39[10]:1161-1168), and analysis included all patients who received ≥1 study dose. †7-point scale (0 "not at all" to 6 "a very great deal"). ‡5-point scale (1 "very hard" to 5 "watery"). §Defined as adequate relief of global IBS symptoms for ≥2 of first 4 weeks posttreatment based on response (yes/no) to weekly question: "In regard to all your symptoms of IBS, as compared with the way you felt before you started the study medication, have you, in the past 7 days, had adequate relief of your IBS symptoms?" ¶Defined as adequate relief of IBS-related bloating for ≥2 of first 4 weeks posttreatment based on response (yes/no) to weekly question: "In regard to your symptoms of bloating, as compared with the way you felt before you started study medication, have you, in the past 7 days, had adequate relief of your IBS symptom of bloating?" **≥5.0% of patients in either group. #Defined as ≥30% decrease from baseline in weekly mean scores for abdominal pain/discomfort and weekly mean stool consistency score <4 for ≥2 of first 4 weeks posttreatment.

AE = adverse event; IBS = irritable bowel syndrome; IBS-D = irritable bowel syndrome with diarrhea; RCT = randomized, controlled trial; SAE = serious adverse event; tid = 3 times daily; URTI = upper respiratory tract infection.

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