Xifaxan® (rifaximin) — New Indication

- On May 27, 2014, Salix announced the FDA approval of Xifaxan (rifaximin) for the treatment of IBS-D in adults.
  - Xifaxan is also indicated for the treatment of patients (≥ 12 years of age) with travelers’ diarrhea caused by noninvasive strains of *Escherichia coli* and for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥ 18 years of age.

- The approval of Xifaxan’s new indication was based on three placebo-controlled trials. In the first two trials, patients were randomly assigned to receive Xifaxan or placebo for 14 days, and then followed for a 10-week treatment-free period. The third trial evaluated repeat courses of Xifaxan.
  - In all three trials, more patients treated with Xifaxan responded or showed improvement in abdominal pain and stool consistency compared to placebo.

- The most common adverse reactions (≥ 2%) with Xifaxan use for the treatment of IBS-D were increased alanine aminotransferase levels and nausea.

- For IBS-D, the recommended dose of Xifaxan is 550 mg orally three times a day for 14 days.
  - Patients may take up to two additional courses if IBS-D symptoms recur in the future.

- For travelers’ diarrhea, the recommended dose of Xifaxan is 200 mg orally three times a day for 3 days. For HE, the recommended dose of Xifaxan is 550 mg orally two times a day.