FDA has approved eluxadoline and rifaximin, two new treatments manufactured by two different companies, for irritable bowel syndrome with diarrhea (IBS-D) in adult men and women.

Eluxadoline, which contains a new active ingredient, is taken orally twice daily with food. The drug activates receptors in the nervous system that can lessen bowel contractions.

Rifaximin can be taken orally three times a day for 14 days for the treatment of abdominal pain and diarrhea in patients with IBS-D. Patients who experience a recurrence of symptoms can be retreated with a 14-day treatment course up to two times. An antibiotic derived from rifampin, rifaximin was previously approved as treatment for travelers’ diarrhea caused by *E. coli* and for reduction of the risk in adult patients of recurring overt hepatic encephalopathy.

The exact mechanism of action of rifaximin for treatment of IBS-D is not known, but it is thought to be related to changes in the bacterial content in the gastrointestinal tract.

Safety and effectiveness of eluxadoline for treatment of IBS-D were established in two double-blind, placebo-controlled clinical trials in which 2,425 patients were randomly assigned to receive eluxadoline or placebo. Results showed eluxadoline was more effective than placebo in simultaneously reducing abdominal pain and improving stool consistency over 26 weeks of treatment.

Safety and effectiveness of rifaximin for treatment of IBS-D were established in three double-blind, placebo-controlled trials. In the first two trials, 1,258 patients were randomly assigned to receive rifaximin or placebo for 14 days and then followed for a 10-week treatment-free period. More rifaximin-treated patients reported improvements in abdominal pain and stool consistency than those on placebo. A third trial evaluated repeat courses of rifaximin because patients...
with IBS-D can develop recurrent signs and symptoms after a single treatment course.

A total of 636 patients with recurrence were randomized to receive either rifaximin or placebo for two additional 14-day courses separated by 10 weeks. More patients treated with rifaximin than placebo were responders in abdominal pain and stool consistency in this phase of the study.

The most common adverse effects in patients treated with eluxadoline include constipation, nausea, and abdominal pain. The most serious known risk is the risk of spasm in the sphincter of Oddi, the smooth muscle that surrounds the end portion of the common bile and pancreatic ducts, which can result in pancreatitis. Eluxadoline should not be used in patients with a history of bile duct obstruction, pancreatitis, severe liver impairment, or severe constipation, or in patients who drink more than three alcoholic beverages per day.

The most common adverse effects in patients treated with rifaximin for IBS-D include nausea and an increase in alanine aminotransferase. If diarrhea does not improve or worsens after treatment with rifaximin, then evaluation for development of a severe infectious diarrhea, Clostridium difficile enterocolitis, should be performed. Caution should be used when using rifaximin in patients with severe liver impairment or when combined with certain other drugs.

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