

FDA approves new drugs for irritable bowel syndrome

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Both treat diarrhea that can strike some with the gastrointestinal disorder.

(HealthDay)—Two new drugs for adults with irritable bowel syndrome with diarrhea (IBS-D) were approved by the U.S. Food and Drug Administration on Wednesday.

"For some people, IBS can be quite disabling, and no one medication works for all <u>patients</u> suffering from this gastrointestinal disorder," Dr. Julie Beitz, director of the Office of Drug Evaluation III in FDA's Center for Drug Evaluation and Research, said in an agency news release.

"The approval of two new therapies underscores the FDA's commitment to providing additional treatment options for IBS patients and their



doctors," she added.

Viberzi (eluxadoline) is a pill that contains a new type of active ingredient, and it is taken twice a day with food. It is designed to activate receptors in the nervous system that can lessen bowel contractions.

Xifaxan (rifaximin) is a pill taken three times a day for 14 days to treat <u>abdominal pain</u> and diarrhea. If symptoms return, patients can repeat the 14-day treatment up to two times.

According to the FDA, Xifaxan is an antibiotic that was previously approved for treatment of travelers' diarrhea caused by E. coli and for adults with recurring overt hepatic encephalopathy, a change in brain function that occurs when the liver can't remove toxins from the blood.

With <u>irritable bowel syndrome</u>, the drug is believed to affect bacterial content in the gastrointestinal tract, the FDA said.

Viberzi's approval was based on two <u>clinical trials</u> that included more than 2,400 patients. Over 26 weeks of treatment, Viberzi was more effective than an inactive placebo in reducing abdominal pain and improving stool consistency, according to the FDA.

Common side effects among patients who took Viberzi were constipation, nausea and abdominal pain.

The agency's approval of Xifaxan was based on three clinical trials that included more than 1,800 patients. Those who took the <u>drug</u> were more likely to report improvements in abdominal pain and stool consistency than those who took a placebo.

Common side effects among patients who took Xifaxan included nausea and higher blood levels of a liver enzyme, the FDA said.



Irritable bowel syndrome affects 10 percent to 15 percent of Americans. People with IBS-D—a subtype of irritable bowel syndrome—have loose or watery stools at least 25 percent of the time.

Viberzi is made by Patheon Pharmaceuticals, Inc. and distributed by Forest Pharmaceuticals, Inc.; both companies are based in Cincinnati. Xifaxan is marketed by Salix Pharmaceuticals, in Raleigh, N.C.

More information: The American Academy of Family Physicians has more about <u>irritable bowel syndrome</u>.

Visit the FDA to learn more about these approvals.

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