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IN BRIEF

Pancreatitis with Eluxadoline (*Viberzi*) in Patients without a Gallbladder

The FDA has warned that eluxadoline (*Viberzi* – Allergan), a mu-opioid receptor agonist and delta-opioid receptor antagonist approved in 2015 for treatment of irritable bowel syndrome with diarrhea (IBS-D),¹ should not be used in patients without a gallbladder because of an increased risk of serious pancreatitis.²

As of February 2017, the FDA had received reports of 118 cases of serious, nonfatal pancreatitis and 2 deaths associated with use of eluxadoline. Both deaths occurred in patients without a gallbladder who developed severe abdominal pain and vomiting shortly after taking the first dose. At least 48 of the cases occurred after only 1 or 2 doses of eluxadoline. Of the 68 patients whose gallbladder status was reported, 56 did not have a gallbladder. Most of the patients without a gallbladder (44/56) were taking the reduced dosage of eluxadoline recommended for such patients (75 mg once/day).

Patients considered at risk for pancreatitis were excluded from the two trials that led to approval of eluxadoline. One case of pancreatitis and 8 cases of abdominal pain with hepatic enzyme elevation associated with sphincter of Oddi spasm occurred with use of eluxadoline in the trials, all in patients without a gallbladder.³

According to the current label, eluxadoline is contraindicated in patients who abuse alcohol (including those who consume >3 servings of alcohol per day) and in those with known or suspected biliary duct, pancreatic duct, or GI tract obstruction, sphincter of Oddi disease or dysfunction, or severe hepatic impairment (Child-Pugh C). It is also contraindicated in those with a history of pancreatitis, structural pancreatic disease, or chronic or severe constipation.

Some alternatives to eluxadoline, which is only modestly more effective than placebo in relieving IBS-D symptoms, are the antidiarrheal loperamide (*Imodium*, and generics), the non-absorbed antibiotic rifaximin (*Xifaxan*), and the 5-HT₃ receptor antagonist alosetron (*Lotronex*, and generics). Taken as needed, loperamide can reduce postprandial urgency and stool frequency, but it does not improve global symptoms of IBS-D. Like eluxadoline, rifaximin has only been modestly effective in relieving symptoms. Because of concerns about severe constipation and ischemic colitis, alosetron should be used only in women with severe, chronic IBS-D that is unresponsive to other drugs.⁴ ■

1. Eluxadoline (*Viberzi*) for irritable bowel syndrome with diarrhea. *Med Lett Drugs Ther* 2016; 58:4.
2. FDA Drug Safety Communication: FDA warns about increased risk of serious pancreatitis with irritable bowel drug *Viberzi* (eluxadoline) in patients without a gallbladder. Available at: www.fda.gov/Drugs/Drug-Safety/ucm546154.htm. Accessed April 13, 2017.
3. AJ Lembo et al. Eluxadoline for irritable bowel syndrome with diarrhea. *N Engl J Med* 2016; 374:242.
4. Drugs for irritable bowel syndrome. *Med Lett Drugs Ther* 2016; 58:121.

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