

Viberzi[™] (eluxadoline) – Safety update

- On March 15, 2017, the [FDA announced](#) that Allergan's [Viberzi \(eluxadoline\)](#) should not be used in patients who do not have a gallbladder.
- Patients who do not have a gallbladder who are taking Viberzi for irritable bowel syndrome with diarrhea (IBS-D) have an increased risk of developing pancreatitis, sphincter of Oddi spasm, and death.
- Symptoms of pancreatitis have occurred with just one or two doses of Viberzi at the recommended dosage for patients who do not have a gallbladder (75 mg) and who do not consume alcohol.
- Viberzi is a schedule IV controlled substance indicated in adults for the treatment of IBS-D.
 - IBS-D affects the large intestine and causes cramping, abdominal pain, bloating, gas, and diarrhea. Viberzi works by decreasing bowel contractions, which leads to less diarrhea.
- Healthcare providers should not prescribe Viberzi to patients who do not have a gallbladder and should consider alternative over-the-counter (OTC) or prescription medicines indicated to treat IBS-D and its related symptoms in these patients.
 - OTC examples include bismuth subsalicylate (eg, [Kaopectate[®]](#), [Pepto-Bismol[™]](#)), [Imodium[®] \(loperamide\)](#) and [Gas-X[®] \(simethicone\)](#). Prescription [Lomotil[®] \(diphenoxylate/atropine\)](#) may be used to treat diarrhea.
 - Other prescription medications indicated to treat IBS-D include [Lotronex[®] \(alosetron\)](#) and [Xifaxan[®] \(rifaximin\)](#).
 - Refer to individual drug labels for specific indication information.
- Patients should stop taking Viberzi right away and seek immediate emergency care if they experience symptoms of pancreatitis or spasm of the sphincter of Oddi, such as new or worsening abdominal pain, or pain in the upper right side of the abdomen that radiates to the back or shoulder. This pain may occur with or without nausea and vomiting.
- Additional FDA recommendations for healthcare providers:
 - Pancreatitis with and without sphincter of Oddi spasm can occur even after the first or second dose of Viberzi, independent of gallbladder status.
 - Viberzi should not be used in the following patients: those who do not have a gallbladder; current or past history of a blockage of the gallbladder or a sphincter of Oddi problem; history of pancreatitis or other pancreas problems, including a blockage of the pancreas; history of serious liver problems; history of chronic or severe constipation; current or past history of intestinal obstruction; or history of alcohol abuse, alcohol addiction, or drinks > 3 alcoholic beverages/day.
 - Patients should be counseled on managing stress and making changes in diet and lifestyle to help control IBS-D symptoms.
- Additional FDA recommendations for patients:
 - Patients should avoid using alcohol and other anti-diarrhea medicines while taking Viberzi.
 - Patients should discuss with their healthcare provider before taking any prescription or OTC medicine to treat diarrhea, constipation or other problems with the bowel or colon. Taking other anti-diarrhea medicines while taking Viberzi can cause severe constipation.

- Patients should discuss how to control IBS-D symptoms with their healthcare provider, especially if they do not have a gallbladder.
- Patients should use Viberzi along with lifestyle changes, such as limiting foods that aggravate symptoms, eating more slowly and not overeating, and avoiding carbonated drinks, which can lead to gas and cramping. Some information can be found at the [National Institute of Diabetes and Digestive and Kidney Diseases](#) website.
- The safety update is from a review of the FDA Adverse Event Reporting System. From May 2015, when Viberzi was first approved, through February 2017, the FDA received 120 reports of serious cases of pancreatitis or death. Seventy-six of these cases resulted in hospitalization, of which two patients died.
 - Some cases of serious pancreatitis or death also reported sphincter of Oddi spasm or abdominal pain.
 - Serious cases of pancreatitis or death occurred after one or two doses of Viberzi while other serious cases occurred with prolonged use.
 - Of the cases that reported gallbladder status, most did not have a gallbladder and were receiving the recommended dosage of Viberzi. Of those that did not have a gallbladder, roughly half did not abuse alcohol, while the remaining cases did not report alcohol use status.
- The FDA is working with Allergan to address the safety concerns with Viberzi use.



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