

An Increased Risk of Serious Pancreatitis with Viberzi

On March 15, 2017, the FDA issued a drug safety warning regarding the risk of developing serious pancreatitis in patients taking Viberzi (eluxadoline) if the patient does not have a gallbladder. Viberzi is an oral tablet medication that is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) that works by decreasing bowel contractions. After completing a review on the medication, the FDA found that these patients are at an increased risk of developing severe pancreatitis that could possibly result in hospitalization or death. From May 2015, when the medication was first approved, through February 2017, the FDA received 120 reports of serious cases of pancreatitis or death. Of the 68 patients who reported their gallbladder status, 56 reported that they did not have a gallbladder while receiving the recommended dose of Viberzi. In addition, two patients that reported not having a gallbladder died. The FDA is currently working with Allergan Pharmaceuticals, the maker of Viberzi, to address these safety concerns.

Patients who have a known history of gallbladder removal should not be prescribed Viberzi and should be prescribed alternative medicines for the treatment of IBS-D. Signs and symptoms of pancreatitis that the patient and healthcare provider should be aware of include: severe upper abdominal pain, nausea, and vomiting. If the patient experiences any of these symptoms while taking Viberzi, they should stop taking the medication and seek medical attention immediately. While the cause of IBS-D is not known, it is known to affect the large intestine and cause loose or watery stools at least 25% of the time. Alternative treatment options include both OTC and prescription medications. For OTC options, patients with IBS-D can consider loperamide (Imodium) to help treat diarrhea symptoms or simethicone (Gas-X) for gas relief. For prescription options, healthcare providers can prescribe alosetron (Lotronex), diphenoxylate/atropine (Lomotil), or rifaximin (Xifaxin). Patients and healthcare providers should report any side effects from taking Viberzi to the FDA immediately.

References:

- FDA Drug Safety Communication. Viberzi (eluxadoline). FDA. March 15, 2017. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm546154.htm>
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- Irritable Bowel Syndrome: Definition & Facts. National Institute of Health. February 2015. Available at: <https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome/definition-facts>
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