

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**PrVIBERZI®  
(eluxadoline tablets)**

Read this carefully before you start taking Viberzi and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Viberzi.

**Serious Warnings and Precautions**

Pancreatitis (inflammation of the pancreas) may occur with Viberzi. Stop using Viberzi and get immediate medical help if you have new or worsening pain in your belly, with or without nausea or vomiting. The pain may feel like it is moving to your back or shoulder. See “Serious side effects and what to do about them”, below.

**What is Viberzi used for?**

Viberzi is used to treat adults with irritable bowel syndrome with diarrhea (IBS-D)

**How does Viberzi work?**

IBS-D is a bowel disorder which causes stomach discomfort, bloating and pain, along with diarrhea.

Viberzi acts on local receptors in the gut and may reduce diarrhea and may help reduce pain.

Viberzi not a cure for IBS-D. If you stop taking Viberzi your symptoms may return in a week.

**What are the ingredients in Viberzi?**

Medicinal ingredients: eluxadoline

Non-medicinal ingredients: colloidal silica, crospovidone, mannitol, magnesium stearate, silicified microcrystalline cellulose, tablet coating (iron oxide red, iron oxide yellow, polyethylene glycol, partially hydrolyzed polyvinyl alcohol, talc, titanium dioxide)

**Viberzi comes in the following dosage forms:**

Viberzi is available in two tablet strengths, 75 mg and 100 mg.

**Do not use Viberzi if you:**

- Are allergic to any ingredient in Viberzi. Make sure to read “What are the ingredients in Viberzi?” above.
- have had a blockage in your bile duct (tube carrying bile from the liver and gallbladder to the intestine).
- have had a sphincter of Oddi problem (muscle that controls the flow of bile and pancreatic

fluid into the intestine).

- do not have a gallbladder
- have had problems with alcohol abuse, alcohol addiction, or drink more than 3 alcoholic drinks a day.
- have had pancreatitis (inflammation of the pancreas) or a blockage in your pancreas.
- have liver disease.
- have had long-lasting (chronic) or severe constipation.
- have had a bowel blockage (intestinal obstruction).
- are taking medicines which may increase the level of eluxadoline in your blood (e.g., OATP1B1 inhibitors such as cyclosporine).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Viberzi. Talk about any health conditions or problems you may have, including if you:**

- are pregnant or plan to become pregnant. Viberzi should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. Viberzi should not be used when breastfeeding.
- have a history of illicit or prescription drug or alcohol abuse.

#### **Other Warnings**

- **Constipation:** Stop taking Viberzi and contact your doctor if you develop severe constipation. See “Serious side effects and what to do about them”, below.
- **Drug Abuse and Dependence:** Viberzi is an opioid. It may lead to psychological dependence or abuse. Use Viberzi only as directed by your doctor.
- **Driving and Using machines:** Viberzi may make you feel sleepy, dizzy or tired. Do not drive or operate machinery until these symptoms have passed.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **The following may interact with Viberzi:**

Some medicines may increase the level of eluxadoline in the blood for example:

- Cyclosporine (used to reduce inflammation).
- Gemfibrozil (used to lower lipid levels).
- Atazanavir, lopinavir, ritonavir or saquinavir (antiretrovirals used to treat HIV).
- Rifampin (antibiotic used to treat infections).

Do not take Viberzi with these medicines.

- Viberzi may increase the level of rosuvastatin (used to treat high cholesterol) in your blood. Talk to your doctor before taking Viberzi if you are taking rosuvastatin.
- Avoid taking Viberzi with drugs that cause constipation including opioids (e.g., fentanyl, oxycodone, hydrocodone, used to treat pain), anticholinergics (e.g., atropine used to treat heart disorders or oxybutynin or tolterodine, used to treat overactive bladder) or alosetron\* (\*not available in Canada).

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

- You may take loperamide occasionally with Viberzi to treat severe diarrhea. Stop taking loperamide right away if you become constipated.
- Your risk of getting pancreatitis is increased if you drink more than 3 alcoholic drinks a day. Limit your use of alcoholic drinks while you are taking Viberzi.

**How to take Viberzi:**

Take Viberzi as prescribed by your healthcare professional.

**Usual adult dose:**

The usual adult dose is 100 mg (1 tablet) twice daily with food. Your healthcare professional may prescribe a lower dose of 75 mg twice daily with food, if you are 65 years of age or older or based on your medical history.

**Overdose:**

If you think you have taken too much Viberzi, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose of Viberzi (delay of > 4 hours), skip that dose and take the next dose at the usual time with food. Do not double your dose.

**What are possible side effects from using Viberzi?**

These are not all the possible side effects you may feel when taking Viberzi. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects reported with Viberzi are:

- Constipation.
- Nausea.
- Abdominal pain.
- Vomiting.
- Bloating.
- Gas.
- Sleepiness.
- Dizziness.
- Fatigue.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b>			
<b>Severe constipation:</b> may present with a difficulty passing stool, sudden belly pain, nausea, vomiting, and abdominal distention (feeling bloated or full).			✓
<b>Allergic reactions:</b> swelling of the face, lips, mouth or throat, shortness of breath or other breathing problems, itching, rash or hives			✓
<b>RARE</b>			
<b>Sphincter of Oddi spasm:</b> new or worsening pain in the belly with or without nausea or vomiting. You may feel pain on the upper right side of your belly, just below the ribs. The pain may feel like it is moving to your back or shoulder.			✓
<b>Pancreatitis:</b> new or worsening pain in your belly, with or without nausea or vomiting. The pain may feel like it is moving to your back or shoulder.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p><b>Reporting Side Effects</b></p> <p>You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.</p> <p><b>3 ways to report:</b></p> <ul style="list-style-type: none"> <li>• Online at <a href="#">MedEffect</a>;</li> <li>• By calling 1-866-234-2345 (toll-free);</li> <li>• By completing a Consumer Side Effect Reporting Form and sending it by: <ul style="list-style-type: none"> <li>- Fax to 1-866-678-6789 (toll-free), or</li> <li>- Mail to: Canada Vigilance Program Health Canada, Postal Locator 1908C Ottawa, ON K1A 0K9</li> </ul> </li> </ul> <p>Postage paid labels and the Consumer Side Effect Reporting Form are available at <a href="#">MedEffect</a>.</p> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
---

**Storage:**

Store your bottle of pills at room temperature (15° to 30°C). Keep out of reach and sight of children.

**If you want more information about Viberzi:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [www.allergan.ca](http://www.allergan.ca), or by calling 1-800-668-6424.

This leaflet was prepared by Allergan Inc.

Last Revised: April 25, 2019

VIBERZI® is a registered trademark Allergan Holdings Unlimited Company, used under license by Allergan Inc.