

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **VIBERZI**®

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 taking 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 the **Serious side effects and what to do about them** table, below, for more information on this and other serious side effects.
- Do not take VIBERZI if you do not have a gallbladder.

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 pain.

VIBERZI is 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, magnesium stearate, mannitol, Opadry II (iron oxide red, iron oxide yellow, polyethylene glycol, partially hydrolyzed polyvinyl alcohol, talc, titanium dioxide), silicified microcrystalline cellulose

VIBERZI comes in the following dosage forms:

Tablets: 75 mg or 100 mg

Do not use VIBERZI if:

- you are allergic to eluxadoline or any of the non-medicinal ingredients in VIBERZI (see **What are the ingredients in VIBERZI?**)

- you have had a blockage in your bile duct (tube carrying bile from the liver and gallbladder to the intestine)
- you have had a sphincter of Oddi problem (muscle that controls the flow of bile and pancreatic fluid into the intestine)
- you do not have a gallbladder
- you have had problems with alcohol abuse, alcohol addiction, or drink more than 3 alcoholic drinks a day
- you have had pancreatitis (inflammation of the pancreas) or a blockage in your pancreas
- you have liver problems
- you have had long-lasting (chronic) or severe constipation
- you have had a bowel blockage (intestinal obstruction)
- you are taking medicines which may increase the level of VIBERZI 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 you should know about:

- **Constipation:** Stop taking VIBERZI and talk to your healthcare professional if you develop severe constipation. See the **Serious side effects and what to do about them** table, below, for more information on this and other serious side effects.
- **Drug Abuse and Dependence:** VIBERZI is an opioid. It may lead to psychological dependence or abuse. Use VIBERZI only as directed by your healthcare professional.
- **Driving and Using Machines:** VIBERZI may make you feel sleepy, dizzy or tired. Give yourself time after taking VIBERZI to see how you feel before driving a vehicle or using machinery.

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

Do NOT take VIBERZI with the following:

- 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)
- eltrombopag (used to treat blood problems)

The following may interact with VIBERZI:

- probenecid (used to treat gout)
- ciprofloxacin, clarithromycin (antibiotics used to treat infections)
- fluconazole (used to treat fungal infections)
- paroxetine, bupropion (used to treat depression and other mental health problems)
- VIBERZI may increase the level of rosuvastatin (used to treat high cholesterol) in your blood. Talk to your healthcare professional 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 problems or oxybutynin or tolterodine, used to treat overactive bladder) or alosetron* (*not available in Canada). Ask your healthcare professional 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 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, or a person you are caring for, have taken too much VIBERZI, contact a 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 to make up for the missed dose.

What are possible side effects from using VIBERZI?

These are not all the possible side effects you may have when taking VIBERZI. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- constipation
- nausea
- abdominal pain

- vomiting
- bloating
- gas
- sleepiness
- dizziness
- fatigue

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Severe constipation: may present with a difficulty passing stool, sudden belly pain, nausea, vomiting, and abdominal distention (feeling bloated or full).			✓
Allergic reactions: swelling of the face, lips, mouth or throat, shortness of breath or other breathing problems, itching, rash or hives.			✓
RARE			
Sphincter of Oddi spasm: 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.			✓
Pancreatitis: 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, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store VIBERZI 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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