

MEDICATION GUIDE
VIBERZI (vye BER zee), CIV
(eluxadoline) tablets

Read this Medication Guide before you start taking VIBERZI and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about VIBERZI?

VIBERZI can cause serious side effects, including:

- **Sphincter of Oddi spasm.** The sphincter of Oddi is a muscular valve that controls the flow of digestive juices (bile and pancreatic juice) to the first part of your small intestine. A sphincter of Oddi spasm can cause an increase in your liver and pancreas enzymes and inflammation of the pancreas (pancreatitis) that can cause sudden stomach-area (abdomen) pain. Your risk of having a sphincter of Oddi spasm is increased if you do not have a gallbladder. This spasm usually happens within the first week of treatment with VIBERZI and usually goes away when treatment with VIBERZI is stopped.
Stop taking VIBERZI and call your doctor if you have new or worsening stomach-area (abdomen) pain or pain in the upper right side of your stomach-area (abdomen) that may move to your back or shoulder, with or without nausea and vomiting.
- **Inflammation of the pancreas (pancreatitis).** Symptoms of pancreatitis usually go away when treatment with VIBERZI is stopped. 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.
Stop taking VIBERZI and call your doctor if you have new or worsening stomach-area (abdomen) pain that may move to your back or shoulder, with or without nausea and vomiting.

What is VIBERZI?

VIBERZI is a prescription medicine used to treat adults who have irritable bowel syndrome with diarrhea (IBS-D).

- VIBERZI is a controlled substance (CIV) because it contains eluxadoline that can be a target for people who abuse prescription medicines or street drugs. Keep your VIBERZI in a safe place, to protect it from theft. Never give your VIBERZI to anyone else, because it may harm them. Selling or giving away this medicine is against the law.

It is not known if VIBERZI is safe and effective in children.

People 65 years old and older have had an increased number of side effects, including serious side effects and stomach problems, while taking VIBERZI than people younger than 65 years old have had.

Who should not take VIBERZI?

Do not take VIBERZI if you:

- have or may have had a blockage in your gallbladder or a sphincter of Oddi problem
- have or had problems with alcohol abuse, alcohol addiction, or drink more than 3 alcoholic drinks a day
- have had inflammation of your pancreas (pancreatitis) or other pancreas problems, including if you have had or may have had a blockage in your pancreas
- have severe liver problems
- have had long-lasting (chronic) or severe constipation, or problems caused by constipation
- have or may have had a bowel blockage (intestinal obstruction)

Talk to your doctor if you are not sure if you have any of these conditions.

What should I tell my doctor before taking VIBERZI?

Before taking VIBERZI, tell your doctor about all of your medical conditions, including if you:

- See **“What is the most important information I should know about VIBERZI?”**
- do not have a gallbladder
- have liver problems
- are pregnant or plan to become pregnant. It is not known if VIBERZI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VIBERZI passes into your breast milk or could harm your baby.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine. VIBERZI and other medicines may affect each other causing side effects.

If you are taking VIBERZI you should not take:

- medicines that cause constipation including:
 - o Lotronex[®] (alosetron)
 - o anticholinergic medicines
 - o opioid pain medicines

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

- Avoid taking loperamide, a medicine used to treat diarrhea, for a long time (chronic use). You may take loperamide occasionally to treat severe diarrhea. **Stop taking loperamide right away if you become constipated.**

How should I take VIBERZI?

- Take VIBERZI exactly as your doctor tells you to take it.
- Take 1 tablet of VIBERZI 2 times each day with food.
- If you miss a dose, take your next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.
- Do not change your dose or stop taking VIBERZI unless your doctor tells you to.
- If you take too much VIBERZI, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking VIBERZI?

- Limit your use of alcoholic drinks while you are taking VIBERZI.
- If you have liver problems, **do not** drive, operate machinery, or do other dangerous activities until you know how VIBERZI affects you.

What are the possible side effects of VIBERZI?

See **“What is the most important information I should know about VIBERZI?”**

The most common side effects of VIBERZI include: constipation, nausea, and abdominal pain. Stop taking VIBERZI and call your doctor if you have constipation that lasts more than 4 days.

These are not all the possible side effects of VIBERZI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VIBERZI?

Store VIBERZI at room temperature between 68°F to 77°F (20°C to 25°C).

Keep VIBERZI and all medicines out of the reach of children.

General Information about the safe and effective use of VIBERZI

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIBERZI for a condition for which it was not prescribed. Do not give VIBERZI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about VIBERZI that is written for health professionals.

What are the ingredients in VIBERZI?**Active ingredient:** eluxadoline**Inactive ingredients:** silicified microcrystalline cellulose, colloidal silica, crospovidone, mannitol, magnesium stearate, and Opadry II (partially hydrolyzed polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow, and iron oxide red).

Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054 USA

© 2015 Actavis. All rights reserved.

For more information, go to www.VIBERZI.com or call 1-800-272-5525.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: May 2015