# For your adult patients with IBS-D, **"VIBERZI™ (eluxadoline) is now available in Canada.**

## May 2017

Dear Pharmacist,

Allergan Pharma Co. ("Allergan") is pleased to announce the launch of VIBERZI<sup>™</sup> in Canada. VIBERZI<sup>™</sup> is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.<sup>1</sup> In clinical trials, VIBERZI<sup>™</sup> improved abnormal stool consistency more prominently than abdominal pain.<sup>1</sup>

VIBERZI<sup>™</sup> provides sustained relief of both abdominal pain and diarrhea in IBS-D through multiple, targeted receptor interactions in the gut.<sup>1-4\*</sup>

VIBERZI<sup>™</sup> also offers convenient, twice-daily dosing: The recommended dosage of VIBERZI<sup>™</sup> is 100 mg taken orally, twice daily with food.<sup>1</sup>

Dose	DIN	UPC
75 mg	02460890	60 tablets: 0 69886 95931 4
100 mg	02460904	60 tablets: 0 69886 95690 0

#### Clinical use:

Use of VIBERZI<sup>™</sup> in patients <18 years of age is not recommended.

#### Contraindications:

- Known or suspected biliary duct obstruction; or sphincter of Oddi disease or dysfunction, and in patients without a gallbladder
- Alcoholism, alcohol abuse or alcohol addiction, or in patients who drink more than 3 alcoholic beverages per day
- A history of pancreatitis; or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
- Hepatic impairment (Child-Pugh Class A, B, and C)
- A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
- Patients on concomitant treatment with potent inhibitors of OATP1B1 (e.g. cyclosporine)

#### **Relevant warnings and precautions:**

- Sphincter of Oddi Spasm
- Increased risk of pancreatitis

• Increased risk of constipation

- Risk for drug abuse/dependence
- Not recommended in pregnant and nursing women

### For more information:

Please consult the Product Monograph at www.allergan.ca for important information relating to adverse reactions, drug interactions, and dosing information not discussed in this piece. The Product Monograph is also available by calling Allergan Inc. at 1-800-668-6424.

# To request more information or a visit from an Allergan representative, e-mail <u>viberzicanada@allergan.com</u>.

\*In pivotal trials for IBS-D, VIBERZI<sup>™</sup> demonstrated simultaneous improvements in both abdominal pain and diarrhea for the primary endpoint: At 12 weeks, the proportion of overall composite responders for VIBERZI<sup>™</sup> 75 mg and VIBERZI<sup>™</sup> 100 mg was 26.2% and 27.0%, respectively, vs. 16.7% of placebo-treated patients (p<0.001 for both doses). At 26 weeks, the proportion of overall composite responders for VIBERZI<sup>™</sup> 75 mg and VIBERZI<sup>™</sup> 75 mg and VIBERZI<sup>™</sup> 100 mg was 26.7% and 31.0%, respectively, vs. 19.5% of placebo-treated patients (p<0.001 for both doses).

Pooled data of 2 Phase III studies with identical 26-week double-blind, placebo-controlled treatment periods. Patients who met the Rome III diagnostic criteria for IBS-D were randomized to receive VIBERZI<sup>III</sup> (75 mg or 100 mg) BID or placebo and evaluated for both efficacy and safety. The primary endpoint was overall composite response: a simultaneous improvement in daily worst abdominal pain score by  $\geq$ 30% compared to the baseline weekly average and reduction in BSS to <5 or absence of concurrent bowel movement for  $\geq$ 50% of the days within the 12- and 26-week time interval.

References: 1. VIBERZI<sup>™</sup> (eluxadoline) Product Monograph, Allergan Pharma Co., January 26, 2017. 2. Lembo AJ, Lacy BE, Zuckerman MJ, *et al.* Eluxadoline for Irritable Bowel Syndrome with Diarrhea. *N Engl J Med.* 2016;374(3):242-253. 3. Supplement to: Lembo AJ, Lacy BE, Zuckerman MJ, *et al.* Eluxadoline for Irritable Bowel Syndrome with Diarrhea. *N Engl J Med.* 2016;374(3):242-253. 4. Wade PR, Palmer JM, McKenney S, *et al.* Modulation of gastrointestinal function by MuDelta, a mixed μ opioid receptor agonist/μ opioid receptor antagonist. *Br J Pharmacol.* 2012;167(5):1111-1125.





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