

CADTH COMMON DRUG REVIEW

Patient Input

VIBERZI (ELUXADOLINE)

(Allergan Pharma Co.)

Indication: Irritable bowel syndrome with diarrhea

CADTH received patient input from:

Gastrointestinal Society

March 16, 2018

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1. About Your Patient Group

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI (Gastrointestinal) Society is committed to improving the lives of people with GI and liver conditions, supporting research, advocating for appropriate patient access to health care, and promoting gastrointestinal and liver health.

Canadian health care professionals request more than 550,000 of our BadGut® Basics patient information pamphlets each year, and tens of thousands of Canadians benefit from our important quarterly publication, the *Inside Tract® | Du coeur au ventre*^{MC} newsletter.

Our free BadGut® Lectures from coast to coast cover various digestive conditions for patients, caregivers, and other interested individuals. We also have dynamic websites in English (www.badgut.org) and French (www.mauxdeventre.org). Organized on a number of topics, GI Society support group meetings offer a wealth of information for those newly diagnosed with a gastrointestinal disorder, as well as those who have lived with a condition for years.

Our highly trained staff and volunteers offer additional patient resources, including responding to information requests and participating in community initiatives. Staff and advisors work closely with health care professionals, other patient groups, and governments at all levels on behalf of GI patients. The GI Society, along with its sister charity, the Canadian Society of Intestinal Research (founded in 1976), has supported a number of significant clinical, basic, and epidemiological GI research.

2. Information Gathering

The GI Society obtained information through printed sources, collective feedback from patients associated with the GI Society who suffer from diarrhea-predominant irritable bowel syndrome (IBS-D), information written by physicians for our publications (newsletter, pamphlets, website), and responses from our online survey of IBS patients, which garnered nearly 3,000 respondents. We were also part of a global look at the IBS patient experience, with a report published in early 2018.

3. Disease Experience

13-20% of Canadians are living with IBS, which is a chronic, often debilitating, functional gastrointestinal disorder, and approximately a third of these have diarrhea-predominant IBS. It is normal to have a bowel movement as frequently as three times a day or as infrequently as three times a week, provided the stool is soft and comfortable to pass. However, a person with IBS-D experiences frequent bowel movements, which can often be watery, along with bowel urgency, bloating, and abdominal pain. Almost everyone experiences diarrhea occasionally, but in IBS-D, this diarrhea is a frequent, painful occurrence. In this group of IBS patients, the digestive system contracts quickly, speeding up transit time for products of digestion.

Seniors, who are already often isolated due to health limitations, suffer further when they cannot participate in social interactions or maintain independence because they are worried about when they might suddenly need to access a washroom or experience severe abdominal pain.

Children may miss out on school and social opportunities, which can have adverse effects on their development. A **working parent** with IBS-D may have to miss work because of chronic diarrhea and/or be unable to effectively care for children or other family members who need them.

One of the most uncomfortable aspects of IBS-D is not knowing when symptoms might strike. Many individuals with IBS-D avoid social gatherings and other outings, because they need to have access to a bathroom at all times, just in case. This leads many to feel embarrassed, self-conscious, and ashamed.

Patients with diarrhea-predominant IBS have told us the following about how it affects their lives:

- “I feel like having IBS rules my life due to the fact that I have to plan my daily activities around toilets and how I'm feeling that day.”

- “I do not simply have diarrhea, it is not like when you have a flu. I will not just get over it.”
- “It is so exhausting, physically and mentally!”
- “[It is] embarrassing to go anywhere as the diarrhea comes on without warning.”
- “It can be very isolating.”
- “At one time, at the early stage, I lost 20lbs in about 4 weeks because I could not eat anything without [getting] diarrhea.”
- “[I] can't eat while working for fear of diarrhea and gas, so [I] become sluggish and get headaches when working.”
- “It limits your social life, and family too. Eating is not out of pleasure as it once was, it is now essential and painful.”
- “It wreaks havoc on your health, how much energy you have, your ability to function normally on a daily basis doing everyday things such as driving, going to shows, working, eating out, always needing to know where a bathroom is.”

4. Experiences With Currently Available Treatments

IBS-D is a serious problem that significantly impairs quality of life. IBS-D sufferers face public stigma and lack of understanding. There are treatments available, but many IBS-D patients do not respond to available treatments.

Diet/exercise: Eating regular well-balanced meals and snacks with high-fibre content, as set in *Canada's Food Guide*, and maintaining an adequate fluid intake, can help many individuals with IBS-D manage diarrhea. Certain types of fibre can help slow down the passage of stool, but this is often not enough for moderate to severe diarrhea.

Physiotherapy: Pelvic dysfunction physiotherapy may include bowel retraining, electrical stimulation, and posture correction. This treatment helps some patients, but usually in combination with other treatments.

Anti-diarrheal medications: Some anti-diarrheal medications work by altering the muscle activity of the intestine to slow down transit time.

Patients who have tried the above treatments have told us:

- “One by one they become ineffective over time. I have to constantly track bowel movements and escalate treatment.”
- “I spent far more than I could afford on products.”
- “They did not work.”

5. Improved Outcomes

Patients want medications that work for them. IBS is a highly-individualized disorder. The causes are unknown, and each person reacts differently to various treatments. When the available treatments do not provide effective relief, patients are unable to meet the normal responsibilities in their lives – toward their employers, families, and communities. Currently, there aren't many treatment options for those with diarrhea-predominant IBS. The most important thing for many IBS-D sufferers is being able to go about day-to-day life normally, without worrying about when their next bout of diarrhea and pain will suddenly occur.

6. Experience With Drug Under Review

Eluxadoline (Viberzi™) is an oral medication approved for the treatment of the multiple symptoms associated with IBS-D in adults. It acts locally in the gut and the body only minimally absorbs this medication. It slows intestinal transit and secretion and reduces abdominal pain. In clinical trials, Viberzi™ showed significant improvements in both bowel habits (e.g., urgency-free days, stool consistency, and frequency), and abdominal symptoms (e.g., abdominal pain and bloating) during the 26-week treatment period. Mild-to-moderate constipation was the most common side effect. We expect the patient population specifically affected by IBS-D will receive Viberzi™ enthusiastically. Viberzi™ could fill a crucial treatment gap for IBS-D patients.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Allergan 2017 for public education, newsletter, pamphlets, and public lectures			✓	
Allergan 2018 for newsletter and pamphlet support (less than for 2017)			✓	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

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Position: Chief Executive Officer

Patient Group: Gastrointestinal Society

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