You Are Cordially Invited to Attend a Professional Lecture

This promotional program is intended to educate healthcare practitioners on

TREATMENT OPTIONS FOR IBS-D AND FOR IBS-C AND CIC:

A CLINICAL REVIEW

Viberzi® (eluxadoline) tablets C IV
75 mg • 100 mg

Linzess® (linaclotide) capsules
72 mcg • 145 mcg • 290 mcg

Featuring

Recent Developments in the Treatment of Altered GI Motility and Visceral Hypersensitivity

Presented by:
Brittany Harris, NP
Jackson, TN
Sponsored by Allergan

Thursday, September 26, 2019 at 6:00 PM

Flatiron Grille
1160 Vann Drive, Jackson, TN 38305
Phone: (731) 668-3528

Please RSVP for this program by using the following link:
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Please reference Meeting ID 55839.

For questions contact your Allergan Representative
Kindle Brasher
Phone: (731) 549-7855

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INDICATIONS AND USAGE

VIBERZI (eluxadoline) is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

IMPORTANT SAFETY INFORMATION FOR VIBERZI

Contraindications

VIBERZI is contraindicated in patients:

- Without a gallbladder.
- With known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction; a history of pancreatitis; or structural diseases of the pancreas.
- With alcoholism, alcohol abuse, alcohol addiction, or who drink more than 3 alcoholic beverages per day.
- With a known hypersensitivity reaction to VIBERZI.
- With severe hepatic impairment.
- With a history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction.

INDICATIONS AND USAGE

LINZESS (linaclotide) is indicated in adults for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION FOR LINZESS

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
LINZESS is contraindicated in patients less than 6 years of age. In nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration. Use of LINZESS should be avoided in patients 6 years to less than 18 years of age. The safety and effectiveness of LINZESS have not been established in patients less than 18 years of age.

Please see additional Important Safety Information for VIBERZI and LINZESS on reverse and accompanying full Prescribing Information.

Viberzi®
(eluxadoline) tablets [C-IV]
75 mg • 100 mg

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Pancreatitis:

- Pancreatitis, with or without sphincter of Oddi spasm, has been reported in patients taking either the 75 mg or 100 mg dosage of VIBERZI, including serious cases resulting in hospitalization, primarily in patients without a gallbladder. Fatal cases have also been reported in patients without a gallbladder. VIBERZI is contraindicated in patients without a gallbladder. Most of the reported cases of serious pancreatitis occurred within a week of starting treatment with VIBERZI and some patients developed symptoms after one to two doses.
- In patients with a gallbladder, evaluate a patient's alcohol intake prior to starting VIBERZI. Instruct patients to avoid chronic or acute excessive alcohol use while taking VIBERZI. Monitor for new or worsening abdominal pain that may radiate to the back or shoulder, with or without nausea and vomiting. Instruct patients to immediately stop VIBERZI and seek medical attention if they experience symptoms suggestive of pancreatitis such as acute abdominal or epigastric pain radiating to the back or shoulder associated with elevations of pancreatic enzymes with or without nausea and vomiting.

Sphincter of Oddi Spasm:

- There is a risk of sphincter of Oddi spasm, resulting in pancreatitis or hepatic enzyme elevation associated with acute abdominal pain (eg, biliary-type pain) in patients taking VIBERZI. Serious adverse reactions of sphincter of Oddi spasm with or without pancreatitis resulting in hospitalization have been reported, primarily in patients without a gallbladder. Cases of serious sphincter of Oddi spasm occurred within a week of starting treatment with VIBERZI and some patients developed symptoms after one to two doses.
- Instruct patients to immediately stop VIBERZI and seek medical attention if they experience symptoms suggestive of sphincter of Oddi spasm such as acute worsening of abdominal pain that may radiate to the back or shoulder with or without nausea and vomiting, associated with elevations of pancreatic enzymes or liver transaminases. Do not restart VIBERZI in patients who developed biliary duct obstruction while taking VIBERZI.

Hypersensitivity Reactions:

- In postmarketing experience, serious hypersensitivity reactions (including anaphylaxis) have been reported following VIBERZI administration. Some of these reactions occurred after the first one or two doses of VIBERZI.
- Instruct patients to immediately stop VIBERZI and seek medical attention if they experience symptoms suggestive of a hypersensitivity reaction.

Constipation:

- Constipation, sometimes requiring hospitalization, has been reported following VIBERZI administration. In postmarketing experience, severe cases with development of intestinal obstruction, intestinal perforation, and fecal impaction, requiring intervention, have also been reported. Instruct patients to stop VIBERZI and immediately contact their healthcare provider if they experience severe constipation. Avoid use with other drugs that may cause constipation.

Adverse Reactions

- The most commonly reported adverse reactions (incidence >5% and greater than placebo) were constipation, nausea, and abdominal pain.

Linzess®
(linaclotide) capsules
72 mcg • 145 mcg • 290 mcg

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- LINZESS is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in patients less than 6 years of age. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.
- Use of LINZESS should be avoided in pediatric patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. The incidence of diarrhea was similar in the IBS-C and CIC populations. Severe diarrhea was reported in 2% of 145 mcg and 290 mcg LINZESS-treated patients, and in <1% of 72 mcg LINZESS-treated CIC patients. If severe diarrhea occurs, dosing should be suspended and the patient rehydrated.

Common Adverse Reactions (incidence ≥2% and greater than placebo)

- In IBS-C clinical trials: diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- In CIC trials of a 145 mcg dose: diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%). In a CIC clinical trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs <1%).

Please see additional Important Safety Information on the front and accompanying full Prescribing Information for VIBERZI and LINZESS.

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