Please join us for a promotional program intended to educate healthcare practitioners

Could it be more than occasional constipation?

Time to have a deeper conversation with your patient

INCLUDING A CLINICAL REVIEW OF LINZESS® (linaclotide) capsules

GUEST SPEAKER:

Sharon Rimon, NP-C Reddy Gl Associates, Mesa, Arizona

Thursday, July 21, 2022 at 6:00 PM

Reforma Cocina & Cantina

4310 N Campbell Avenue (St. Philip's Plaza) Tucson, Arizona 85718

For questions, contact your AbbVie Representative Jennifer Staples (520) 308-8163



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

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE

LINZESS is contraindicated in patients less than 2 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.

Please see additional Important Safety Information on pages 1 and 2, including Boxed Warning.

Please see full <u>Prescribing Information</u>, including Boxed Warning, or visit https://www.rxabbvie.com/pdf/linzess_pi.pdf.

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this program is limited to healthcare professionals who practice in relevant specialties. AbbVie tracks and reports payments and transfers of value to healthcare professionals under applicable state and federal reporting obligations.



IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- LINZESS is contraindicated in patients less than 2 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

Risk of Serious Dehydration in Pediatric Patients Less Than 2 Years of Age

 LINZESS is contraindicated in patients less than 2 years of age. In neonatal mice, linaclotide increased fluid secretion as a consequence of agedependent elevated GC-C agonism which was associated with increased mortality within the first 24 hours due to dehydration. There was no age-dependent trend in GC-C intestinal expression in a clinical study of children 2 to less than 18 years of age; however, there are insufficient data available on GC-C intestinal expression in children less than 2 years of age to assess the risk of developing diarrhea and its potentially serious consequences in these patients. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established.

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 $\geq 2\%$ 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 trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs <1%).

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