



Discover a Different Mechanism of Action to Treat IBS-C: A Case-based Discussion



Darren Brenner, MD

Professor of Medicine and Surgery
Northwestern University – Feinberg
School of Medicine
Chicago, IL

MONDAY, MAY 08, 2023

9:30 AM – 10:15 AM, CT

Digestive Disease Week® 2023
McCormick Place - DDW Theatre 1
2301 S. King Dr, Chicago, IL

The Product Theatre content and views expressed therein are those of the sponsor and not of Digestive Disease Week®.

INDICATION

IBSRELA (tenapanor) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats administration of tenapanor caused deaths presumed to be due to dehydration. Avoid use of IBSRELA in patients 6 years to less than 12 years of age. The safety and effectiveness of IBSRELA have not been established in patients less than 18 years of age.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Risk of Serious Dehydration in Pediatric Patients

- IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human equivalent 2 years to less than 12 years).

- Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

Diarrhea

Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in IBSRELA-treated patients (incidence $\geq 2\%$ and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs $<1\%$), flatulence (3% vs 1%) and dizziness (2% vs $<1\%$).

Please see accompanying full Prescribing Information, including Boxed Warning, at [IBSRELA.com/PI](https://www.ardelyx.com/PI).

This is a promotional program sponsored by Ardelyx. No CME/CE credit will be provided. In accordance with the PhRMA Code on Interactions with Healthcare Professionals, this program is intended only for healthcare professionals who will find its content clinically relevant to their practice. Accordingly, non-healthcare professionals (ie, spouses and other guests) may not attend. Invitation is extended only to those HCPs whose attendance would not violate compliance with state law requirements in which such HCP is licensed to practice.

