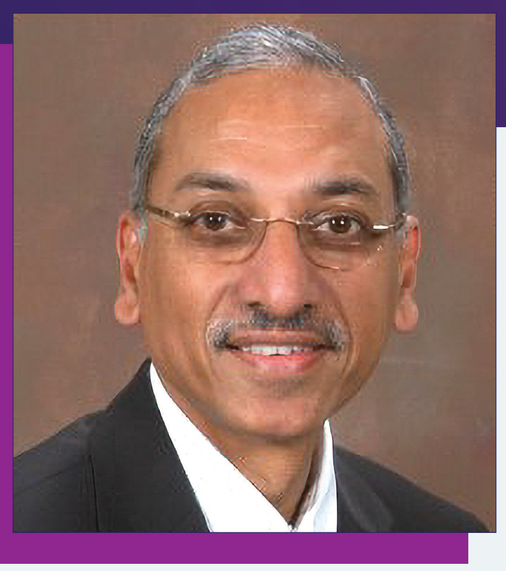
IBSRELA® (tenapanor) tablets 50 mg BID

# Integrating a Different Mechanism of Action, a Different Class of Therapy, Into the Treatment of Adults With IBS-C[1*]



## Satish Rao, MD, PhD, FRCP, FACG, AGAF

## SUNDAY, MAY 4, 2025
**12:50 PM–1:35 PM PT**

**2025 DDW**
San Diego Convention Center
DDW Theater 2

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## 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 ≥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 full Prescribing Information, including Boxed Warning, next to this display.**

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*Mechanism of Action=NHE3 Inhibitor.

**Reference: 1.** IBSRELA [prescribing information]. Waltham, MA: Ardelyx, Inc.; 2022.

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