



## Now approved

The only prescription medication FDA approved for Irritable Bowel Syndrome with Constipation (IBS-C) in women 18 years and over

Introducing a new 8 mcg dose

No restriction on duration of use

- Based on safety studies up to 52 weeks\*
- Physicians and patients should periodically assess the need for continued therapy



**Please see Important Safety Information on reverse side.**

\*12- to 16-week double-blind studies and a 36-week open-label study.



## Prescription **AMITIZA**

# Now for the treatment of IBS-C in women 18 years and over

## Stocking Information

NDC	Product	Strength	Size
64764-080-60	AMITIZA	8 mcg	60



## Product Information

1-877-TAKEDA-7 or visit [www.amitiza.com](http://www.amitiza.com)

## Indication

- AMITIZA® (lubiprostone) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (8 mcg) in women  $\geq 18$  years old.

## Important Safety Information

- AMITIZA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating physician to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. AMITIZA should be used during pregnancy only if the benefit justifies the potential risk to the fetus. Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.
- Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their physician.
- AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment and inform their physician if the diarrhea becomes severe.
- Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within 3 hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their physician.
- In clinical trials of patients with Irritable Bowel Syndrome with Constipation (8 mcg), the most common adverse reactions (incidence  $>4\%$ ) were nausea (8%), diarrhea (7%), and abdominal pain (5%).

**Please see accompanying complete Prescribing Information.**

