

FIRST TIME GENERIC APPROVAL

Brand Name	Amitiza
Generic Name	lubiprostone
Drug Manufacturer	Sucampo Pharma Americas LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First time generic approval

FDA APPROVAL DATE

November 30, 2020

LAUNCH DATE

FDB Addition Date – January 12, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

New Drug Application (NDA): 021908

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Amitiza is a chloride channel activator indicated for the treatment of:

- Irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old
- Opioid-induced constipation (OIC) in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
- Chronic idiopathic constipation (CIC) in adults

MECHANISMS OF ACTION

Lubiprostone is a locally acting chloride channel activator that enhances a chloride-rich intestinal fluid secretion without altering sodium and potassium concentrations in the serum. Lubiprostone acts by specifically activating CIC-2, which is a normal constituent of the apical membrane of the human intestine, in a protein kinase A–independent fashion. By increasing intestinal fluid secretion, lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated with chronic idiopathic constipation. Patch clamp cell studies in human cell lines have indicated that the majority of the beneficial biological activity of lubiprostone and its metabolites is observed only on the apical (luminal) portion of the gastrointestinal epithelium. Lubiprostone, via activation of apical CIC-2 channels in intestinal epithelial cells, bypasses the antisecretory action of opiates that results from suppression of secretomotor neuron excitability. Activation of

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CIC-2 by lubiprostone has also been shown to stimulate recovery of mucosal barrier function and reduce intestinal permeability via the restoration of tight junction protein complexes in ex vivo studies of ischemic porcine intestine.

DOSE FORM AND STRENGTH

Capsules: 8 mcg and 24 mcg

DOSE & ADMINISTRATION

Recommended Dosage

- CIC and OIC: 24 mcg twice daily.
- IBS-C: 8 mcg twice daily.
- See full prescribing information for dosage adjustment by indication and degree of hepatic impairment.

Administration Instructions

- Swallow capsules whole and do not break apart or chew.
- Take capsules with food and water.
- Assess periodically the need for continuous therapy

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