

Lubistone™

Lubiprostone INN Capsule

Presentation

Lubistone™ 8 Capsule: Each capsule contains Lubiprostone INN 8 mcg.

Lubistone™ 24 Capsule: Each capsule contains Lubiprostone INN 24 mcg.

Description

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 ClC-2, which is a normal constituent of the apical membrane of the human intestine.

By increasing intestinal fluid secretion, Lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated with constipation.

Indications and usage

- Chronic Idiopathic Constipation
- Opioid-induced Constipation (OIC) in adults with chronic non-cancer pain
- Irritable Bowel Syndrome with Constipation (IBS-C)

Dosage and administration

Chronic Idiopathic Constipation and Opioid-induced Constipation:

The recommended dose is 24 mcg twice daily orally with food and water.

Dosage in patients with hepatic impairment: For patients with moderately impaired hepatic function, the recommended starting dose is 16 mcg twice daily. For patients with severely impaired hepatic function, the recommended starting dose is 8 mcg twice daily.

Irritable Bowel Syndrome with Constipation:

The recommended dose is 8 mcg twice daily orally with food and water.

Dosage in patients with hepatic impairment: Dosage adjustment is not required for patients with moderately impaired hepatic function. For patients with severely impaired hepatic function, the recommended starting dose is 8 mcg once daily. If tolerated then dose can be increased to 8 mcg twice daily.

Side effects

Diarrhea, full or bloated feeling or pressure in the stomach, nausea, stomach pain, swelling of abdominal or stomach area, dyspnea.

Precautions

Nausea: Patients taking Lubiprostone may experience nausea. Concomitant administration of food with Lubiprostone may reduce symptoms of nausea.

Diarrhea: Lubiprostone should not be prescribed to patients that have severe diarrhea.

Bowel Obstruction: In patients with symptoms suggestive of mechanical gastrointestinal obstruction, perform a thorough evaluation to confirm the absence of an obstruction prior to initiating therapy with Lubiprostone.

Contraindication

Lubiprostone is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Use in pregnancy and lactation

Pregnancy Category C.

It is not known whether lubiprostone is excreted in human milk. Because lubiprostone increases fluid secretion in the intestine and intestinal motility, human milk-fed infants should be monitored for diarrhea. Caution should be exercised when Lubiprostone is administered to a nursing woman.

Drug interaction

There is a possibility of a dose-dependent decrease in the efficacy of Lubiprostone in patients using diphenylheptane opioids.

Overdose

Adverse reactions due to overdose may include: nausea, diarrhea, vomiting, dizziness, headache, abdominal pain, flushing/hot flash, retching, dyspnea, pallor, stomach discomfort, anorexia, asthenia, chest discomfort, dry mouth, hyperhidrosis, and syncope.

Commercial pack

Lubistone™ 8 capsule: Each box contains 2 blister strips of 10 capsules.

Lubistone™ 24 capsule: Each box contains 2 blister strips of 10 capsules.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh

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LBS