GUTLAX™ 24

Lubiprostone 24 mcg

COMPOSITION

Gutlax™ 24 Licap: Each liquid filled capsule contains Lubiprostone INN 24mcg.

PHARMACOLGY

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.It 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 chronic idiopathic constipation.

INDICATION

- Chronic Idiopathic Constipation (CIC) in adults.
- 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.

DOSAGE & 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.

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 having 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.

CONTRAINDICATIONS

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

USE IN PREGNANCY & LACTATION

Pregnancy

Following oral administration, concentrations of lubiprostone in plasma are below the level of quantitation. Limited available data with lubiprostone use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Animal reproduction studies did not show an increase in structural malformations.

Lactation

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.

PEDIATRICS

Safety and effectiveness have not been established in pediatric patients less than 6 years of age.

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.

STORAGE

Protect from light and moisture. Store below 30^0 C. Keep all medicine out of the reach of children.

HOW SUPPLIED

Gutlax™ 24 Licap: Each box contains 20 liquid filled capsules.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh