

Lubigut

Lubiprostone INN

Composition

Lubigut 8 Capsule: Each Capsule contains Lubiprostone INN 8 mcg.

Lubigut 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 chronic idiopathic constipation.

After administration, Lubiprostone and its metabolites is observed only on the apical (luminal) portion of the gastrointestinal epithelium. Additionally, activation of ClC-2 by Lubiprostone has been shown to stimulate recovery of mucosal barrier function via the restoration of tight junction protein complexes.

Indications

Lubigut (Lubiprostone) is indicated for the treatment of

- Chronic Idiopathic Constipation in adults
- Irritable bowel syndrome with constipation in women \geq 18 years old
- Opioid-induced Constipation (OIC) in adults

Dosage & Administration

Indications	Dosage
Chronic Idiopathic Constipation	24 mcg twice daily
Opioid-induced Constipation	24 mcg twice daily
Irritable Bowel Syndrome with Constipation (IBS-C)	8 mcg twice daily

Side effects

Nausea, diarrhea, headache, abdominal pain, abdominal distension and flatulence.

Contraindications

Patients with known or suspected mechanical gastrointestinal obstruction should not receive Lubiprostone.

Precautions

Patients may experience nausea; concomitant administration of food may reduce this symptom. Do not prescribe for patients that have severe diarrhea. Patients taking Lubiprostone may experience dyspnea within an hour of first dose. This symptom generally resolves within 3 hours, but may recur with repeat dosing. Evaluate patients with symptoms suggestive of mechanical gastrointestinal obstruction prior to initiating treatment with Lubiprostone.

Use in Pregnancy & Lactation

Pregnancy Category C. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Lubiprostone is excreted in human milk. Caution should be exercised when Lubiprostone is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been studied.

Geriatric Use

Chronic Idiopathic Constipation: The safety & efficacy of Lubiprostone in the elderly (\geq 65 years of age) patients remain constant in both young and older patients. Elderly patients taking Lubiprostone (any dosage) experienced a lower incidence rate of associated nausea compared to the overall study population taking Lubiprostone.

IBS-C: The safety & efficacy of Lubiprostone in the elderly (\geq 65 years of age) patients remain constant in both young and older patients.

Renal Impairment: Lubiprostone has not been studied in patients who have renal impairment.

Hepatic Impairment: Lubiprostone has not been studied in patients who have hepatic impairment.

Drug Interactions

Based upon the results of in vitro human microsome studies, there is low likelihood of drug–drug interactions. In vitro studies using human liver microsomes indicate that cytochrome P450 isoenzymes are not involved in the metabolism of Lubiprostone. Based on the available information, no protein binding–mediated drug interactions of clinical significance are anticipated. Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of Lubiprostone.

Storage

Store at cool (temperature below 25° C), dry place, protect from moisture & light. Keep away from the reach of children.

Packaging

Lubigut 8 Capsule: Each Box contains 3x10's capsules in blister pack.

Lubigut 24 Capsule: Each Box contains 2x10's capsules in blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh