Lubicon

Lubiprostone

Composition:

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

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

Pharmacology:

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. After administration, Lubiprostone and its metabolites are observed only on the apical (luminal) portion of the gastrointestinal epithelium. Additionally, activation of ClC-2 by Lubiprostone recovers mucosal barrier function via restoration of tight junction protein complexes. Lubiprostone relieves symptoms within 24 hours.

Indication:

Chronic Idiopathic Constipation: Lubiprostone is indicated for the treatment of chronic idiopathic constipation in adults.

Opioid-induced Constipation: Lubiprostone is indicated for the treatment of opioid-induced constipation in adults.

Irritable Bowel Syndrome with Constipation: Lubiprostone is the only FDA approved drug for the treatment of irritable bowel syndrome with constipation in women > 18 years old.

Dose and administration:

Chronic Idiopathic Constipation: Lubiprostone 24 mcg twice daily orally with food and water.

Opioid-induced Constipation: Lubiprostone 24 mcg twice daily orally with food and water.

Irritable Bowel Syndrome with Constipation: Lubiprostone 8 mcg should be taken twice daily orally with food and water.

Contra-indication:

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

Warning & precautions:

Nausea: Patients taking Lubiprostone may experience nausea. If this occurs, 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, confirm the absence of such an obstruction prior to initiating therapy with Lubiprostone.

Side effects:
Nausea, vomiting, loose stools, dry mouth, stomach discomfort, headache, dizziness etc.

Use in pregnancy & lactation:
Pregnancy Category C. Lubiprostone should be used in pregnant mother if the potential benefits justifies the potential risk to the fetus. It is not known whether Lubiprostone is excreted in human milk.

Use in children & adolescents:
Safety and effectiveness in children & adolescents has not been studied.

Geriatric use:
Irritable Bowel Syndrome with Constipation: The safety and efficacy of Lubiprostone in the elderly (>65years age) patients remains constant in both young and older patients.

Renal Impairment: Lubiprostone has not been studied in patients who have renal impairment.
Hepatic Impairment: Reduce the dosage in patients with moderate and severe hepatic impairment.

Drug interaction:
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.

Overdose:
Adverse reactions due to overdose are nausea, diarrhea, vomiting, dizziness, headache & abdominal pain.

Storage:
Keep out of the reach of children. Store in a cool & dry place below 25°C, protect from light.

Packing:
Lubicon™ 8 Capsule: Each box contains 30 capsules in Alu-Alu blister packs.
Lubicon™ 24 Capsule: Each box contains 12 capsules in Alu-Alu blister packs.

Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.

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