

Laxibat 5

Elobixibat INN 5 mg



Composition

Laxibat 5 Tablet: Each film coated tablet contains Elobixibat Hydrate INN equivalent to Elobixibat 5 mg.

Pharmacology

Elobixibat inhibits bile acid reabsorption via ileal bile acid transporter (IBAT) expressed on the epithelial cells of the terminal ileum and thereby increases the amount of bile acid passing into the large intestinal lumen. Bile acid promotes the secretion of water and electrolytes into the large intestinal lumen and enhances the colonic motility. Thus, induces the therapeutic effect on constipation.

Indication

Chronic idiopathic constipation (except for constipation associated with organic diseases).

Dosage & Administration

The usual adult dose for oral use is 10 mg once daily as Elobixibat before meal. The dosage may be adjusted depending on the patient's symptoms but must not exceed the highest dose of 15 mg per day.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients
- Patients with a documented intestinal obstruction associated with a tumor or hernia or with the suspicion of such conditions. Intestinal obstruction may be aggravated.

Side Effects

Generally, Elobixibat is well tolerated in patients with chronic constipation. In clinical studies, the side effects include abdominal pain, diarrhea, nausea, abdominal discomfort, soft faeces, abdominal distension, liver function test abnormalities. If liver function test anomalies are detected, patient's symptoms should be monitored carefully, if necessary, Elobixibat should be discontinued.

Precautions & Warnings

Precaution concerning indication: No clinical experience of use in drug-induced and disease-induced constipations.

Precaution concerning dosage and administration: Elobixibat may cause abdominal pain or diarrhea; dose reduction, drug withdrawal, or discontinuation should be considered depending on the patient's symptoms. The need for continuing treatment with Elobixibat should be carefully evaluated on a regular basis to avoid continuing aimless administration.

Careful administration: In patients with serious liver disorder, Elobixibat may fail to achieve its expected efficacy due to biliary obstruction or reduced bile acid secretion, etc.

Overdose Effects

There is no data on overdose of the drug, do not exceed the dosing indicated of the drug. Actively monitor for timely response.

Interactions

Elobixibat should be administered with care when co-administered with the following drugs:

- Bile acid preparations, ursodeoxycholic acid, chenodeoxycholic acid: The inhibitory effect of Elobixibat on ileal bile acid transporter (IBAT) may interfere with reabsorption of bile acid preparations.
- Aluminum-containing antacids, sucralfate hydrate, aldoxa, etc: These drugs absorb bile acids in the gastrointestinal tract and may attenuate the effect of Elobixibat.
- Cholestyramine, colestimide: These drugs absorb bile acids and may attenuate the effect of Elobixibat.
- Digoxin, dabigatran etexilate methanesulfonate: Because of the inhibitory effect of Elobixibat on P-glycoprotein, the blood levels of these drugs may elevate and enhance their effects
- Midazolam: The blood level of midazolam may decrease, and the effect of midazolam may decrease

Use in Special populations

Use in the elderly

Since the elderly generally have reduced physiological functions, cautions should be exercised, such as reducing the dose.

Use in children

Safety has not been established in low-birth-weight infants, neonates, nursing infants, infants, or pediatric patients (no clinical experience).

During Pregnancy

Should be used in pregnant women and women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

During Lactation

It is advised that lactating women should avoid Elobixibat. If treatment with Elobixibat is essential, breast feeding must be discontinued during treatment.

Storage

Do not store above 25°C. Protect from light. Keep out of reach of children.

Packaging

Laxibat 5 Tablet: Each carton contains 3×10's tablets in Blister pack.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh

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