

## ELOBETRA

### For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **ELOBETRA** [Elobixibat Tablets 5 mg]  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

#### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** 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. Therefore, Elobixibat induces the therapeutic effects on constipation.

**INDICATION:** For treatment of chronic constipation (except for constipation associated with organic disease).

**DOSAGE AND 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.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients.

Patients with medical history of hypersensitivity to the ingredients of Elobixibat. Patients with a documented intestinal obstruction associated with a tumor or hernia or with the suspicion of such conditions. (Intestinal obstruction may be aggravated).

**WARNINGS & PRECAUTIONS:** **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, and the need for continuing treatment with Elobixibat should be carefully evaluated on a regular basis to avoid continuing aimless administration. *Careful Administration (Elobixibat should be administered with care in the following patients):* Patient with serious liver disorder. [Elobixibat may fail to achieve its expected efficacy in patients with biliary obstruction or reduced bile acid secretion, etc.]. **Precaution Concerning Use:** **Precaution Concerning the Dispensing of the Drug:** Patients who are given drugs supplied in PTP package must be instructed to remove the drugs from the PTP (Press through Package) sheet before taking drugs. *Caution for Usage Drug Compatibility:* Because there are no studies on drug compatibility, do not mix this drug with other drugs. *Use in the Elderly:* Since the elderly generally have reduced physiological functions, cautions should be exercised, such as reducing the dose.

**DRUG INTERACTIONS:** Bile acid preparations Ursodeoxycholic acid, chenodeoxycholic acid, Aluminum-containing antacids Sucralfate hydrate, aldioxa, etc. Cholestyramine, colestimide, Digoxin, dabigatran etexilate methanesulfonate, Midazolam.

**ADVERSE REACTIONS:** Major adverse reactions included: abdominal pain and diarrhea. Other Adverse Reactions: **Hepatic:** Liver function test abnormal (ALT(GPT) increased, AST(GOT) increased). **Central and peripheral nervous system:** Headache, dizziness. **Cardiovascular:** Hot flush. **Gastrointestinal:** abdominal distension, Nausea, abdominal pain upper, abdominal discomfort, faeces soft. **Hypersensitivity:** Urticaria, rash. **Hematologic:** Eosinophil count increased, anaemia, vitamin E increased. **Others:** CK (CPK) increased LDL decreased, LDL/ HDL ratio decreased.

**MARKETED BY:**



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)