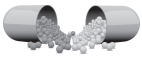

Dexilend

Dexlansoprazole INN

Delayed Release Capsule

Composition

Dexilend 30 : Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.
Dexilend 60 : Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

Description

Dexilend (Dexlansoprazole) delayed-release capsule is a Proton Pump Inhibitor (PPI), that inhibits gastric acid secretion. **Dexilend** (Dexlansoprazole) is the R-enantiomer of lansoprazole (A racemic mixture of the R- and S-enantiomers). **Dexilend** (Dexlansoprazole) is supplied as a Dual Delayed Release (DDR) formulation in a capsule for oral administration. **Dexilend** (Dexlansoprazole) capsule contains a mixture of two types of enteric coated granules with different p^H-dependent dissolution profiles.

Mechanism of Action

Dexilend (Dexlansoprazole) is a PPI that suppresses gastric acid secretion by specific inhibition of the (H^+/K^+)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, **Dexilend** (Dexlansoprazole) blocks the final step of acid production.

Pharmacokinetics

The formulation of **Dexilend** (Dexlansoprazole) utilizing Dual Delayed Release technology results in plasma concentration-time profile with two distinct peaks; the first peak occurs 1 to 2 hours after administration, followed by a second peak within 4 to 5 hours. No accumulation of Dexlansoprazole occurs after multiple once daily doses of **Dexilend** (Dexlansoprazole) 30 mg or 60 mg. After oral administration of **Dexilend** (Dexlansoprazole) 30 mg or 60 mg to healthy subjects, mean C_{max} and AUC values of Dexlansoprazole increased approximately dose proportionally. Dexlansoprazole is extensively metabolized in the liver and excreted by urine.

Indications

• *Healing of Erosive Esophagitis:* **Dexilend** (Dexlansoprazole) is indicated for healing of all grades of Erosive Esophagitis (EE) for up to 8 weeks • *Maintenance of Healed Erosive Esophagitis:* **Dexilend** (Dexlansoprazole) is indicated to maintain healing of EE and relief of heartburn for up to 6 months • *Symptomatic Non-Erosive Gastroesophageal Reflux Disease:* **Dexilend** (Dexlansoprazole) is indicated for the treatment of heartburn associated with symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD) for 4 weeks.

Dosage and Administration

Dexilend (Dexlansoprazole) dosing recommendations

Indication	Recommended Dose	Frequency
Maintenance of Healed EE and relief of heartburn	30 mg	Once daily
Symptomatic Non-Erosive GERD	30 mg	Once daily for 4 weeks
Healing of EE	60 mg	Once daily for up to 8 weeks

Important Administration Information

- **Dexilend** (Dexlansoprazole) can be taken without regard to food or the timing of food.
- **Dexilend** (Dexlansoprazole) should be swallowed whole.
- Alternatively, **Dexilend** (Dexlansoprazole) capsules can be administered as follows:
    - Open capsule.
    - Sprinkle intact granules on one table spoon.
    - Swallow immediately. Granules should not be chewed.

Missed Dose

If a capsule is missed at its usual time, it should be taken as soon as possible. But if it is too close to the time of the next dose, only the prescribed dose should be taken at the appointed time. A double dose should not be taken.

Pregnant women and Nursing women

Pregnancy Category B.
Dexlansoprazole is probably safe for use during pregnancy, although the full risks are currently unknown. It is not known whether Dexlansoprazole is excreted in human milk.

Geriatrics

No dosage adjustment is necessary for elderly patients.

Pediatrics

Safety and effectiveness of **Dexilend** (Dexlansoprazole) in patients below 12 years age have not been established yet.

Renal Impairment

No dosage adjustment is necessary for patients with renal impairment.

Hepatic Impairment

No adjustment of Dexlansoprazole is necessary for patients with mild hepatic impairment. A maximum daily dose of 30 mg for patients with moderate hepatic impairment may be considered.

Contraindication

Dexilend (Dexlansoprazole) is contraindicated in patients with known hypersensitivity to any component of the formulation.

Side-effects

Diarrhea, abdominal pain, nausea, upper respiratory tract Infection, vomiting & flatulence.

Precautions

Gastric malignancy, *Clostridium difficile* associated diarrhea, bone fracture, hypomagnesemia, concomitant use of Dexlansoprazole with Methotrexate.

Drug Interaction

Atazanavir, Warfarin, Tacrolimus, Clopidogrel & Methotrexate.

Overdose

There have been no reports of significant overdose of Dexlansoprazole. Multiple doses of Dexlansoprazole 120 mg and a single dose of Dexlansoprazole 300 mg did not result in any severe adverse events.

Storage

Store in a dry & cool place, protected from light. Keep out of reach of children.

Packaging

Dexilend 30 : Each carton contains 5 x 10's capsules in Alu-Alu blister pack.
Dexilend 60 : Each carton contains 3 x 8's capsules in Alu-Alu blister pack.

Manufactured by

ZISKA PHARMA

Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh