

Lantidex[®]

Dexlansoprazole INN

Description: Lantidex[®] (Dexlansoprazole) capsule is a Proton Pump Inhibitor (PPI), which inhibit gastric acid secretion. Dexlansoprazole is the R-enantiomer of lansoprazole. Dexlansoprazole is supplied as a Dual Delayed Release (DDR) formulation in a capsule for oral administration. Dexlansoprazole capsule contains a mixture of two types of enteric coated granules with different pH-dependent dissolution profiles.

Mode of action: 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, Dexlansoprazole blocks the final step of acid production.

Pharmacokinetics: The formulation of Lantidex[®] (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 Dexlansoprazole. After oral administration of Dexlansoprazole to healthy subjects, mean C_{max} and AUC values of Dexlansoprazole increased approximately dose proportionally. Dexlansoprazole extensively metabolized in the liver and excreted by urine.

Composition: Lantidex[®] 30 mg Capsule: Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.

Lantidex[®] 60 mg Capsule: Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

Indications: *Healing of Erosive Esophagitis:* Dexlansoprazole is indicated for healing of all grades of Erosive Esophagitis (EE) for up to 8 weeks.

Maintenance of Healed Erosive Esophagitis: Dexlansoprazole is indicated to maintain healing of EE and relief of heartburn for up to 6 months.

Symptomatic Non-Erosive Gastroesophageal Reflux Disease: Dexlansoprazole is indicated for the treatment of heartburn associated with symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD) for 4 weeks.

Dosage & administration

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

Contraindications: Patients with known hypersensitivity to any component of the formulation.

Side effects: Diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting and flatulence.

Use in pregnancy & lactation: Pregnancy Category B. It is not known whether Dexlansoprazole is excreted in human milk.

Precautions: Precaution should be taken if patients have gastric malignancy, *Clostridium difficile* associated diarrhea, bone fracture, hypomagnesemia.

Drug interactions: Concomitant of Dexlansoprazole with Atazanavir, Ampicillin esters, Digoxin, Ketoconazole, Warfarin, Tacrolimus and Methotrexate should not be used.

Over dosage: 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 severe adverse events.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Lantidex[®] 30 mg Capsule: Each carton contains 10X3 capsules in Alu-Alu blister pack.

Lantidex[®] 60 mg Capsule: Each carton contains 6X3 capsules in Alu-Alu blister pack.