

Sanbur®

Dexlansoprazole INN

Description: Sanbur® (Dexlansoprazole) tablet is a Proton Pump Inhibitor (PPI), which inhibits gastric acid secretion. Dexlansoprazole is the R-enantiomer of Lansoprazole. Dexlansoprazole is supplied as a Dual Delayed Release (DDR) formulation in a tablet for oral administration. Dexlansoprazole tablet contains a mixture of two types of enteric coated MUPS pellets 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 Sanbur® (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 Cmax and AUC values of Dexlansoprazole are increased approximately dose proportionally. Dexlansoprazole is extensively metabolized in the liver and excreted by urine.

Composition: Sanbur® 30 mg Tablet: Each tablet contains Dexlansoprazole enteric coated MUPS pellets 150.00 mg equivalent to Dexlansoprazole INN 30 mg.

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 Erosive Esophagitis	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 administration of Dexlansoprazole with Atazanavir, Ampicillin esters, Digoxin, Ketoconazole, Warfarin, Tacrolimus and Methotrexate should be avoided.

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

Sanbur® 30 mg Tablet: Each carton contains 10X3 tablets in Alu-Alu blister pack.