

# 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<sup>+</sup>/K<sup>+</sup>-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 C<sub>max</sub> 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.