

# Gerdnil®

## Dexlansoprazole

### COMPOSITION:

Gerdnil® 30 Capsule: Each Capsule contains Dexlansoprazole enteric coated pellets equivalent to Dexlansoprazole INN 30 mg.

Gerdnil® 60 Capsule : Each Capsule contains Dexlansoprazole enteric coated pellets equivalent to Dexlansoprazole INN 60 mg.

### PHARMACOLOGY:

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

### INDICATION:

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

### DOSE & ADMINISTRATION:

Gerdnil® Capsule 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 Erosive Esophagitis:	60 mg	Once Daily for up to 8 weeks

\* Gerdnil® Capsule can be taken without regard to food or the timing of food.

\* Gerdnil® Capsule should be swallowed whole.

\* Alternatively, Gerdnil® Capsule can be administered as follows:

- Open capsule.
- Sprinkle intact granules on one table spoon.
- Swallow immediately. Granules should not be chewed.

### CONTRA-INDICATION:

Dexlansoprazole is contra-indicated in patients with known hypersensitivity to any component of the formulation.

### WARNING AND PRECAUTION:

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

### SIDE EFFECTS:

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

### USE IN PREGNANCY & LACTATION:

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.

### USE IN CHILDREN & ADOLESCENTS:

Dexlansoprazole is not recommended in patients below 12 years of age.

### DRUG INTERACTION:

Atazanvir, Warfarin, Tacrolimus, Clopidogrel and 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 and cool place below 30° C temperature and keep away from light and moisture. keep out of reach of children.

### PACKING:

Gerdnil® 30 Capsule: Each box contains 6 X 10's capsules in Alu-Alu blister pack.

Gerdnil® 60 Capsule: Each box contains 3 X 10's capsules in Alu-Alu blister pack.



Manufactured by

**Team Pharmaceuticals Ltd.**

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