

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⁺/K⁺)-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, hypomagnensemia, 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 4 X 15'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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