Dexila
Dexlansoprazole INN

Composition:
Dexila 30 mg Capsule: Each capsule contains Dexlansoprazole INN 30 mg as dual delayed release enteric coated pellets.

Pharmacology: The active ingredient Dexila (dexlansoprazole) dual delayed-release capsule, a proton pump inhibitor inhibits gastric acid secretion by specific inhibition of the H+/K+ ATPase in the gastric parietal cell. Dexlansoprazole is the R-enantiomer of lansoprazole. Dexlansoprazole is stable when exposed to light. Dexlansoprazole is more stable in neutral and alkaline conditions than acidic conditions. By acting specifically on the proton pump, Dexlansoprazole blocks the final step of acid production. The formulation of Dexila (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.

Indications
- Healing of Erosive Esophagitis
- Maintenance of Healed Erosive Esophagitis
- Relief of Acidity & heartburn
- Symptomatic Non-Erosive Gastroesophageal Reflux Disease

Dosage and administration:
Dexlansoprazole is available as capsules in 30 mg and 60 mg strengths for adult use. Directions for use in each indication are summarized in Table.

Dexlansoprazole Dosing Recommendations

Indication	Recommended Dose	Frequency
Healing of Erosive Esophagitis	60 mg	Once daily for up to 8 weeks
Maintenance of Healed Erosive Esophagitis	30 mg	Once daily for up to 6 months
Relief of acidity & heartburn	30 mg	Once daily
Symptomatic Non-Erosive GERD	30 mg	Once daily for up to 4 weeks

Contraindication
Dexlansoprazole is contraindicated in those patients who have known hypersensitivity to any other component of the formulation.

Warnings and Precautions
Gastric Malignancy: Symptomatic response with Dexila not precludes the presence of gastric malignancy.

Clostridium Difficile Associated Diarrhea: PPI therapy may be associated with an increased risk of Clostridium difficile associated diarrhea.

Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.

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Hypomagnesemia: Hypomagnesemia has been reported rarely with prolonged treatment with PPIs.

Side effects: Adverse events are rarely seen such as Headache, diarrhea and abdominal pain.

Use In Pregnancy And Lactation:
Pregnancy Category B. Teratology studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to Dexlansoprazole . There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Because Dexlansoprazole is likely to be excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Use in Children & adolescents:
Safety and effectiveness of dexlansoprazole in pediatric patients (less than 18 years of age) have not been established.

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

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 severe adverse events.

Storage
Store in a cool (below 30°C) and dry place, protect from light. Keep all medicines out of the reach of children.

How Supplied:
Dexila-30 Capsule: Each box contains 3X10's capsules in Alu-Alu blister pack.

Goodman
Manufactured by:
Goodman Pharmaceuticals Ltd.
Better Health For All
Bhangnahati, Sreepur, Gazipur, Bangladesh