

# DLP

Dexlansoprazole Capsule

## Composition

**DLP 30 Capsule:** Each capsule contains Dexlansoprazole INN 30 mg (as Enteric Coated Pellets)

**DLP 60 Capsule:** Each capsule contains Dexlansoprazole INN 60 mg (as Enteric Coated Pellets)

## Description

DLP (Dexlansoprazole) delayed release capsule has been characterized as a gastric Proton Pump Inhibitor (PPI) that blocks the final step of gastric acid production. It is the R-enantiomer of Lansoprazole (a racemic mixture of the R and S-enantiomers). DLP (Dexlansoprazole) capsule contains enteric coated pellets with different pH - dependent dissolution profiles. The formulation of DLP (Dexlansoprazole) utilizes Dual Delayed Release (DDR) technology which results in plasma concentration-time profile with two distinct peaks; the first peak occurs within 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 DLP.

## Indications

DLP (Dexlansoprazole) is a Proton Pump Inhibitor used to treat-

1. Healing of all grades of Erosive Esophagitis
2. Maintenance of healed Erosive Esophagitis
3. Heartburn associated with Non-Erosive Gastroesophageal reflux disease (GERD)

## Dosage and Administration

Indications	Dose	Duration
Healing of Erosive Esophagitis	60 mg once daily	Up to 8 weeks
Maintenance of healed Erosive Esophagitis and relief of heartburn	30 mg once daily	Up to 6 months
Symptomatic Non-Erosive GERD	30 mg once daily	Up to 4 weeks

## Contraindications

Dexlansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

## Side Effects

Diarrhea, abdominal pain, nausea, vomiting, flatulence etc.

## Precautions

Patients taking concomitant Warfarin may require monitoring for increased International Normalized Ratio (INR) and Prothrombin time. Increased INR and Prothrombin time may lead to abnormal bleeding and even death.

## Use In Pregnancy and Lactation

Dexlansoprazole is considered a US FDA pregnancy Category B drug. This means that Dexlansoprazole is probably safe for use during pregnancy, although the full risks are currently unknown.

## Drug Interactions

Dexlansoprazole may interfere with the absorption of drugs for which gastric pH is important for bioavailability (e.g., Ampicillin esters, Digoxin, Iron salts, Ketoconazole).

## 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 below 30°C & dry place, away from light. Keep out of the reach of children.

## Packing

**DLP 30 Capsule:** Each box contains 3 blister packs with each blister of 10 capsules.

**DLP 60 Capsule:** Each box contains 3 blister packs with each blister of 10 capsules.

Manufactured by:

 **GENERAL**  
Pharmaceuticals Ltd.  
Mouchak, Kaliakair, Gazipur, Bangladesh

22060338-V00