

Lanso[®]D[™]

Dexlansoprazole 30 mg & 60 mg

COMPOSITION

Lanso D[™] 30 capsule: Each delayed release capsule contains Dexlansoprazole INN 30 mg as dual delayed release pellets.

Lanso D[™] 60 capsule: Each delayed release capsule contains Dexlansoprazole INN 60 mg as dual delayed release pellets.

DESCRIPTION

Lanso D[™] (Dexlansoprazole) delayed release capsule has been characterized as a 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). Dexlansoprazole capsule contains a mixture of two type enteric coated pellets with different pH-dependent dissolution profiles.

The formulation of **Lanso D[™]** (Dexlansoprazole) utilizes Dual Delayed Release (DDR) technology which results in Plasma concentration-time profile with two distinct peaks; the first peak occurs within 1 hour of administration, followed by a second peak within 4 to 5 hours. No accumulation of Dexlansoprazole occurs after multiple once daily doses of Lanso D[™] 30 mg of 60 mg.

INDICATION & USES

Lanso D[™] (Dexlansoprazole) is a Proton Pump Inhibitor (PPI) used to treat-

- Relief of heartburn
- Healing of all grades of Erosive Esophagitis
- Maintenance of healed Erosive Esophagitis
- Treatment of non-erosive GERD

DOSAGE & ADMINISTRATION

Lanso D[™] (Dexlansoprazole) capsule is administered orally. The recommended doses of Dexlansoprazole for adults are as follows:

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

SIDE EFFECT

Adverse events are rarely seen; such as diarrhea, abdominal pain, nausea, vomiting, flatulence etc.

PRECAUTION

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.

USE IN PREGNANCY & LACTATION

There are no studies with dexlansoprazole use in pregnant women to inform a drug-associated risk..

CONTRAINDICATION

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

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 single dose of Dexlansoprazole 300 mg did not result in any severe adverse events.

STORAGE

Store below 30°C, protected from light and moisture.

COMMERCIAL PACK

Lanso D[™] 30 Capsule: Each box contains 30 capsules in alu-alu blisters.

Lanso D[™] 60 Capsule: Each box contains 30 capsules in alu-alu blisters.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Gazipur, Bangladesh

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