DLS

Dexlansoprazole

COMPOSITION:

DLS 30 Capsule: Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.
DLS 60 Capsule: Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

PHARMACOLOGY:

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

Mechanism of Action

DLS (Dexlansoprazole) is a PPI that suppresses gastric acid secretion by specific inhibition of the (H^+/K^+)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, **DLS** (Dexlansoprazole) blocks the final step of acid production.

Pharmacokinetics

The formulation of **DLS** (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 **DLS** (Dexlansoprazole) 30 mg or 60 mg. After oral administration of **DLS** (Dexlansoprazole) 30 mg or 60 mg to healthy subjects, mean C max and AUC values of Dexlansoprazole increased approximately dose proportionally. Dexlansoprazole is extensively metabolized in the liver and excreted by urine.

INDICATION:

- *Healing of Erosive Esophagitis:* **DLS** (Dexlansoprazole) is indicated for healing of all grades of Erosive Esophagitis (EE) for up to 8 weeks.
- *Maintenance of Healed Erosive Esophagitis:* **DLS** (Dexlansoprazole) is indicated to maintain healing of EE and relief of heartburn for up to 6 months.
- *Symptomatic Non-Erosive Gastroesophageal Reflux Disease:* **DLS** (Dexlansoprazole) is indicated for the treatment of heartburn associated with symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD) for 4 weeks.

DOSAGE AND ADMINISTRATION:

DLS (Dexlansoprazole) 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 EE	60 mg	Once daily for up to 4 weeks

CONTRAINDICATION:

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

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SIDE EFFECT:
Diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting & flatulence.

WARNING & PRECAUTION:
Gastric malignancy, *Clostridium difficile* associated diarrhea, bone fracture, hypomagnesaemia, concomitant use of Dexlansoprazole with Methotrexate.

USE IN PREGNANCY AND 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 AND ADOLESCENTS:
No dosage adjustment is necessary for elderly patients. Safety and effectiveness of **DLS** (Dexlansoprazole) in patients below 12 years age have not been established yet.

DRUG INTERACTION:
Atazanavir, Warfarin, Tacrolimus, Clopidogrel & Methotrexate.

OVERDOSAGE:
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 cool and dry place (below 30°C), protected from light and moisture. Keep out of reach of children.

PACKING:
DLS 30 Capsule: Each box contains 3x10/5x10 capsules in Alu Alu blister pack.
DLS 60 Capsule: Each box contains 3x10/5x10 capsules in Alu Alu blister pack.

Manufactured by:

MEDICON **MEDICON Pharmaceuticals Ltd.**
Mirpur, Dhaka, Bangladesh