

# DDR

Capsule



## Dexlansoprazole INN

### COMPOSITION

**DDR 30 Capsule** : Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.

**DDR 60 Capsule** : Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

### PHARMACOLOGY

**DDR** (Dexlansoprazole) delayed-release capsule is a Proton Pump Inhibitor (PPI) which suppresses gastric acid secretion by specific inhibition of the (H<sup>+</sup>/K<sup>+</sup>)-ATPase in the gastric parietal cell. By acting specifically on the proton pump, **DDR** (Dexlansoprazole) blocks the final step of acid production. Dexlansoprazole is the R-enantiomer of lansoprazole (A racemic mixture of the R- and S-enantiomers). **DDR** (Dexlansoprazole) is supplied as a Dual Delayed Release (DDR) formulation in a capsule for oral administration. **DDR** (Dexlansoprazole) capsule contains a mixture of two types of enteric coated granules with different pH-dependent dissolution profiles. The dual delayed release formulation of **DDR** results in a dexlansoprazole 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. After oral administration, mean C<sub>max</sub> and AUC value of Dexlansoprazole increased approximately dose proportionally. Dexlansoprazole is extensively metabolized in the liver and excreted by urine.

### INDICATIONS

#### Healing of Erosive Esophagitis :

**DDR** (Dexlansoprazole) is indicated for healing of all grades of erosive esophagitis (EE) for up to 8 weeks.

#### Maintenance of Healed Erosive Esophagitis :

**DDR** (Dexlansoprazole) is indicated to maintain healing of EE and relief of heartburn for up to 6 months.

#### Symptomatic Non-Erosive Gastroesophageal Reflux Disease :

**DDR** (Dexlansoprazole) is indicated for the treatment of heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD) for 4 weeks.

### DOSAGE AND ADMINISTRATION

**Route of administration** : Oral.

**DDR (Dexlansoprazole) Dosing Recommendations** :

**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 8 weeks

**OR AS DIRECTED BY THE PHYSICIAN.**

### IMPORTANT ADMINISTRATION INFORMATION

- **DDR** (Dexlansoprazole) can be taken without regard to food.
- **DDR** (Dexlansoprazole) should be swallowed whole.
- Alternatively, **DDR** (Dexlansoprazole) capsules can be administered as follows:
  - Open capsule
  - Sprinkle intact granules on one tablespoon
  - Swallow immediately.
- Granules should not be chewed.

### MISSED DOSE

If a capsule is missed at its usual time, it should be taken as soon as possible. But if it is too close to the time of the next dose, only the prescribed dose should be taken at the appointed time. A double dose should not be taken.

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

Gastric Malignancy, *Clostridium difficile* Associated Diarrhea, Bone fracture, Hypomagnesemia, and concomitant use of Dexlansoprazole with Methotrexate.

### SIDE EFFECTS

**Common side effects** : Diarrhea, abdominal pain, nausea, vomiting & flatulence.

**Rare side effects** : No data available.

### USE IN PREGNANCY AND LACTATION

**Pregnancy** : Pregnancy Category B. There is no adequate and well-controlled studies with Dexlansoprazole in pregnant women.

**Lactation** : There is no adequate and well-controlled studies with Dexlansoprazole in lactating mother.

### USE IN CHILDREN & ADOLESCENTS

Safety and effectiveness of Dexlansoprazole in patients below 12 years age have not been established.

### GARIATRIC USE

No dose adjustment is necessary for elderly patients.

### RENAL IMPAIRMENT

No dose adjustment of Dexlansoprazole is necessary for patients with renal impairment.

### HEPATIC IMPAIRMENT

No dose adjustment for Dexlansoprazole is necessary for patients with mild hepatic impairment. A maximum daily dose of Dexlansoprazole 30 mg should be considered for patients with moderate hepatic impairment.

### DRUG INTERACTIONS

**With medicine** : Atazanavir, Warfarin, Tacrolimus, Clopidogrel & Methotrexate.

**With food & others** : No data available.

### 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 death or other severe adverse events.

### STORAGE

Store below 30° C temperature & in a dry place, protected from light. Keep all medicines out of reach of children.

### PACKING

**DDR 30 Capsule**: Each box contains 6X10 capsules in Alu-Alu blister strips.

**DDR 60 Capsule**: Each box contains 3X10 capsules in Alu-Alu blister strips.

\* Further information is available on request.

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Manufactured by:

**The ACME Laboratories Ltd.**  
Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness