

# RELOZA DR™ Capsule (Dexlansoprazole)

## COMPOSITION:

### RELOZA DR 30 mg Capsule:

Each capsule contains:  
Dexlansoprazole (as delayed release pellets) ..... 30 mg.

Product Specs.: Innovator

### RELOZA DR 60 mg Capsule:

Each capsule contains:  
Dexlansoprazole (as delayed release pellets) ..... 60 mg.

Product Specs.: Innovator

## INDICATIONS:

Healing of all grades of erosive esophagitis (EE).

Maintaining healing of EE and relief of heartburn.

Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).

## Posology:

Healing of EE: 60 mg once daily for up to 8 weeks.

Maintenance of healed EE: 30 mg once daily for up to 6 months.

Symptomatic non-erosive GERD: 30 mg once daily for 4 weeks.

Controlled studies did not extend beyond 6 months.

## Special Populations:

Use in patients with hepatic impairment: No adjustment is necessary for patients with mild hepatic impairment (Child-Pugh Class A). Consider a maximum daily dose of 30 mg for patients with moderate hepatic impairment (Child-Pugh Class B). No studies have been conducted in patients with severe hepatic impairment (Child-Pugh Class C).

## METHOD OF ADMINISTRATION:

For oral use only. Capsules should be swallowed whole and should not be chewed. May be administered with or without food.

## CONTRAINDICATIONS:

Hypersensitivity to the active substance or to any of the excipients. Hypersensitivity and anaphylaxis have been reported with use. Acute interstitial nephritis has been reported with other proton pump inhibitors (PPIs), including lansoprazole.

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

### Gastric Malignancy:

Symptomatic response does not preclude the presence of gastric malignancy.

### Acute Interstitial Nephritis:

Acute interstitial nephritis has been observed in patients taking PPIs including lansoprazole. Discontinue if acute interstitial nephritis develops.

### Cyanocobalamin (vitamin B<sub>12</sub>) Deficiency:

Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B<sub>12</sub>) caused by hypo- or achlorhydria.

### Clostridium Difficile Associated Diarrhea:

Published observational studies suggest that PPI therapy like may be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized patients.

### Bone Fracture:

Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.

### Hypomagnesemia:

Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy.

### Concomitant Use with Methotrexate:

Literature suggests that concomitant use of PPIs with methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities.

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## PREGNANCY & LACTATION:

There are no adequate and well-controlled studies with Dexlansoprazole in pregnant women therefore should be used during pregnancy only if clearly needed. Because no information is available regarding the use during breastfeeding therefore alternative treatments with better established safety profiles during breastfeeding are preferable.

### Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed.

## ADVERSE EFFECTS:

The most common adverse reactions (≥2%) documented are diarrhea, abdominal pain, nausea, URTI, vomiting, flatulence. The most common adverse reaction resulting in discontinuation in controlled clinical studies was diarrhea (0.7%).

## DRUG INTERACTIONS:

Dexlansoprazole is likely to substantially decrease the systemic concentrations of the HIV protease inhibitor atazanavir. Co-administration of PPIs in healthy subjects and in transplant patients receiving MMF has been reported to reduce the exposure to the active metabolite, mycophenolic acid (MPA). Use Dexlansoprazole with caution in transplant patients receiving MMF. Patients treated with Dexlansoprazole and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time. Concomitant administration of Dexlansoprazole and tacrolimus may increase whole blood levels of tacrolimus, especially in transplant patients who are intermediate or poor metabolizers of CYP2C19.

## OVERDOSE:

Dexlansoprazole is not expected to be removed from the circulation by hemodialysis. If an overdose occurs, treatment should be symptomatic and supportive.

### Pharmacological properties:

The active ingredient in DEXILANT (dexlansoprazole) delayed-release capsules, a proton pump inhibitor, is (+)-2-[(R)-{[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl] methyl} sulfinyl]-1H-benzimidazole, a compound that inhibits gastric acid secretion. Dexlansoprazole is the R-enantiomer of lansoprazole. Dexlansoprazole is a PPI that 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, dexlansoprazole blocks the final step of acid production.

## INSTRUCTIONS:

– Store below 30°C.

– Protect from heat, sunlight & moisture.

– Keep out of the reach of children.

– To be sold on the prescription of a registered medical practitioner only.

## PRESENTATION:

RELOZA DR 30 mg Capsule : Pack of 3 x 10 capsules.

RELOZA DR 60 mg Capsule : Pack of 3 x 10 capsules.

Manufactured by:  
CCL Pharmaceuticals (Pvt.) Ltd.  
Plot No. 710, Sundar Industrial Estate, Raiwind Road Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:



Manufactured for:  
CCL Pharmaceuticals (Pvt.) Ltd.  
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ہدایات:  
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔  
گرمی، دھوپ اور نمی سے بچائیں۔  
بچوں کی پہنچ سے دور رکھیں۔  
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔