

Dual Delayed Release Capsules

Composition

Onedex 30 Capsule: Each Dual Delayed Release capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.

Onedex 60 Capsule: Each Dual Delayed Release capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

Pharmacology

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

Indication

Dexlansoprazole is indicated for the treatment of below indication:

1. Healing of all grades of Erosive Esophagitis
2. Maintaining healing of Erosive Esophagitis
3. Heart burn associated with non-erosive Gastroesophageal Reflux Disease (GERD)

Dose and Administration

a) *Route of administration: Oral*

Indication	Recommended Dose	Frequency
Healing of erosive esophagitis	60 mg	Once daily for up to 8 weeks
Maintenance of Healed erosive esophagitis and relief of heartburn	30 mg	Once daily for up to 6 months
Symptomatic Non-Erosive GERD	30 mg	Once daily for up to 4 weeks

Important Administration Information

- Can be taken without regard to food or the timing of food.
- Should be swallowed whole capsule.
- Alternatively, capsules can be administered as follows:
 - √ Open capsule.
 - √ Sprinkle intact granules on one table spoon.
 - √ 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.

Contra-indication

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

Warning & Precaution

Gastric malignancy, Clostridium difficile associated diarrhea, bone fracture, hypomagnesemia, concomitant use of Dexlansoprazole with Methotrexate.

Renal Impairment: No dosage adjustment is necessary for patients with renal impairment.

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

Side effects

Adverse events are rarely seen, such as-

a) **Common:** Diarrhea, abdominal pain, nausea, upper respiratory tract Infection, vomiting & flatulence.

b) **Rare:** Low Thyroid Hormone Levels, Hemolytic Anemia, Pancytopenia etc.

Use in pregnancy & 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 & Adolescents

Geriatric use: No dosage adjustment is necessary for elderly patients.

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

Drug Interaction

a) **With Medicine:** Dexlansoprazole may interfere with the absorption of drugs for which gastric pH is important for bioavailability (e.g., Ampicillin esters, Digoxin, iron salts, Ketoconazole).

b) **With food & others:** No significant differences in mean intragastric pH were observed between fasted and various fed conditions.

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. Protect from light and moisture. Keep all medicines out of reach of children.

Packing

Onedex 30 Capsule: Each box contains 60 (6X10's) capsules in Alu-Alu blister pack.

Onedex 60 Capsule: Each box contains 30 (3X10's) capsules in Alu-Alu blister pack.