

Canalia

Dexlansoprazole INN

Composition:

Canalia-30 Capsule: Each capsule contains Dexlansoprazole INN 30 mg as enteric coated pellets.

Canalia-60 Capsule: Each capsule contains Dexlansoprazole INN 60 mg as enteric coated pellets.

Pharmacology:

Canalia (Dexlansoprazole) delayed release capsule has been characterized as a gastric 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).

Indications:

Canalia Capsule is indicated for

- Treating heartburn associated with symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD)
- Healing of all grades of Erosive Esophagitis (EE)
- Maintaining healing of EE and relief of heartburn

Dosage and Administration:

Canalia (Dexlansoprazole) capsule is administered orally before or after food. The recommended doses of Dexlansoprazole for adults are as follows:

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

Contraindications:

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

Warnings and Precautions:

No dosage adjustment is necessary for patients with mild hepatic impairment. A maximum daily dose of 30 mg for patients with moderate hepatic impairment can be considered. No studies have been conducted in patients with severe hepatic impairment.

No dosage adjustment is necessary in patients with renal impairment.

Side Effects:

Most commonly reported adverse reactions are diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting etc.

Use in Special Group:

Use in Pregnancy & Lactation: There are no adequate and well-controlled studies with Dexlansoprazole in pregnant women. Dexlansoprazole should be used during pregnancy only if clearly needed. It is not known whether Dexlansoprazole is excreted in human milk, so it may be taken cautiously.

Use in Children: Dexlansoprazole in patients under the age of 12 years has not been studied.

Use in Geriatric Patients: No dosage adjustment is needed in geriatric patients.

Drug Interaction:

Dexlansoprazole may interfere with the absorption of other drugs where gastric pH is an important determinant of oral bioavailability (e.g. Atazanavir, Warfarin, Tacrolimus, Ampicillin Esters, Digoxin, Iron salts, Methotrexate, Ketoconazole).

Overdose:

There have been no reports of significant overdose of Dexlansoprazole. A single dose of Dexlansoprazole 300 mg did not result severe adverse events.

Storage:

- Store below 30°C, keep in dry place & protect from light
- Keep out of the reach of children

Packing:

Canalia-30 Capsule: Each box contains 60 Capsules in alu-alu blister pack.

Canalia-60 Capsule: Each box contains 30 Capsules in alu-alu blister pack.