SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product:

LANSpure® DR 30

Dexlansoprazole Delayed Release Capsules 30 Mg

2. Qualitative and quantitative composition:

Each delayed release capsule contains:

Dexlansoprazole 30mg

(As delayed released pellets)

Excipients ..... q.s.

Approved colour used in empty capsule shell.

(for the full list of excipients, see section 6.1)

3. Pharmaceutical form:

Hard Gelatin Capsule.

A Pink/CT coloured size '4' hard gelatin capsule containing orange- and off-white-coloured pellets.

4. Clinical particulars

4.1 Therapeutic indications

Lanspure® DR 30 (dexlansoprazole delayed release capsules) is indicated for:

Healing of Erosive Esophagitis

Dexlansoprazole delayed-release capsules are indicated for healing of all grades of erosive esophagitis (EE) for up to 8 weeks.

Maintenance of Healed Erosive Esophagitis

Dexlansoprazole delayed-release capsules are indicated to maintain healing of EE for up to 6 months.

Symptomatic Non-Erosive Gastroesophageal Reflux Disease

Dexlansoprazole delayed-release capsules are indicated for the treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks.

4.2 Posology and method of administration

Posology.

- Healing of Erosive Esophagitis: 60 mg once daily for up to 8 weeks.
- Maintenance of Healed Erosive Esophagitis: 30 mg once daily
- Symptomatic Non-Erosive Gastroesophageal Reflux Disease (GERD): 30 mg once daily for 4 weeks

Special populations

Hepatic impairment

No adjustment for dexlansoprazole delayed-release capsules 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)

Renal impairment
No dosage adjustment is necessary for elderly patients or for patients with renal impairment.

Method of administration:
Lanspure® DR 30 can be taken without regard to food or the timing of food. Lanspure® DR 30 should be swallowed whole with plenty of water.
Alternatively, dexlansoprazole delayed-release capsules can be opened and administered as follows;

- Open capsule
- Sprinkle intact granules on one tablespoon of applesauce
- Swallow immediately. Granules should not be chewed.

4.3 Contraindications
Dexlansoprazole delayed-release capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.
Hypersensitivity and anaphylaxis have been reported with dexlansoprazole delayed-release capsules use.

4.4 Special warnings and precautions for use
General
Symptomatic response with dexlansoprazole does not preclude the presence of gastric malignancy.
Clostridium Difficile-Associated Diarrhea: Decreased gastric acidity due to any means, PPIs, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with PPIs can lead to an increased risk of gastrointestinal infections such as Salmonella, Campylobacter and Clostridium difficile.
Concomitant Use with Methotrexate: Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. A temporary withdrawal of the PPI may be considered in some patients receiving treatments with high dose methotrexate.
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
Cyanocobalamin (Vitamin B12) Deficiency: The prolonged use of PPIs may impair the absorption of protein-bound Vitamin B12 and may contribute to the development of cyanocobalamin (Vitamin B12) deficiency.
Gastrointestinal: Long-term use of dexlansoprazole is associated with an increased risk of fundic gland polyps, especially beyond one year. Most fundic gland polyps are asymptomatic. Use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
Immune: Severe Cutaneous Adverse Reactions: Severe cutaneous adverse reactions (SCARs), including Stevens Johnson syndrome (SJS), toxic

epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) and erythema multiforme have been reported in association with the use of PPIs. Discontinue dexlansoprazole at the first signs or symptoms of SCARs or other signs of hypersensitivity and consider further evaluation. At the time of prescription, patients should be informed of the signs and symptoms, and advised to monitor closely for skin reactions.

Subacute cutaneous lupus erythematosus: Subacute cutaneous lupus erythematosus (SCLE) has been reported with the use of PPIs. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping dexlansoprazole.

Monitoring and Laboratory Tests: During treatment with antisecretory drugs, chromogranin A (CgA) increases due to decreased gastric acidity. Increased CgA levels may interfere with investigations for neuroendocrine tumours. To avoid this interference, dexlansoprazole treatment should be stopped 14 days before CgA measurements.

Musculoskeletal: 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. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines.

4.5 Interaction with other medicinal products and other forms of interaction

Drug Interactions with Antiretroviral Drugs

- PPIs have been reported to interact with some antiretroviral drugs. The clinical importance and the mechanisms behind these interactions are not always known. A change in gastric pH may change the absorption of the antiretroviral drug. Other possible mechanisms are via CYP2C19.
- Rilpivirine: Co-administration is contraindicated due to significant decrease in rilpivirine exposure and loss of therapeutic effect.
- Atazanavir and Nelfinavir: Co-administration with atazanavir or nelfinavir is not recommended due to decreased atazanavir and nelfinavir.
- Saquinavir: If Dexlansoprazole is co-administered with saquinavir/ritonavir, caution and monitoring for potential saquinavir toxicities, including gastrointestinal symptoms, increased triglycerides, deep vein thrombosis and QT prolongation, are recommended. Dose reduction of saquinavir should be considered from the safety perspective for individual patients
- Drugs with pH-dependent absorption (e.g., ampicillin esters, digoxin, iron salts, ketoconazole, erlotinib, mycophenolate mofetil): Dexlansoprazole may interfere with absorption of drugs for which gastric pH is important for bioavailability.

- Warfarin: Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time.
- Tacrolimus: Concomitant tacrolimus use may increase tacrolimus whole blood concentrations, especially in transplant patients who are intermediate or poor metabolizers of CYP2C19.
- Methotrexate: Dexlansoprazole may increase serum levels of methotrexate. In high dose methotrexate administration, a temporary withdrawal of Dexlansoprazole may need to be considered.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Pregnancy Category B.

There are no adequate and well controlled studies with dexlansoprazole in pregnant women. There were no adverse fetal effects in animal reproduction studies of dexlansoprazole in rabbits. Because animal reproduction studies are not always predictive of human response, dexlansoprazole delayed-release capsules should be used during pregnancy only if clearly needed.

A reproduction study conducted in rabbits at oral dexlansoprazole doses up approximately 9 times the maximum recommended human dexlansoprazole dose (60 mg per day) revealed no evidence of impaired fertility or harm to the fetus due to dexlansoprazole. In addition, reproduction studies performed in pregnant rats with oral lansoprazole at doses up to 40 times the recommended human lansoprazole dose and in pregnant rabbits at oral lansoprazole doses up to 16 times the recommended human lansoprazole dose revealed no evidence of impaired fertility or harm to the fetus due to Lansoprazole.

Lactation: It is not known whether dexlansoprazole is excreted in human milk. However, lansoprazole and its metabolites are present in rat milk following the administration of lansoprazole. As many drugs are excreted in human milk, and because of the potential for tumorigenicity shown for lansoprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines.

This medicine may cause dizziness or somnolence. It is advised that you do not perform any activities such as driving a vehicle or operating machinery if you experience any of these symptoms during treatment with this medicine.

4.8 Undesirable effects

The most common adverse drug reactions (occurring in at least 1% of subjects) reported in adult patients treated with Dexlansoprazole in placebo and positive-controlled trials were diarrhea, abdominal pain, headache, nausea, vomiting, flatulence, and constipation. The adverse reaction profile observed in adolescent patients (12 to 17 years of age) was similar to that of adults. In controlled clinical trials, the most common adverse reaction leading to discontinuation from dexlansoprazole delayed-release capsules therapy was diarrhoea (0.7%).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose.
There have been no reports of significant overdose of Dexlansoprazole.
Dexlansoprazole is not expected to be removed from the circulation by hemodialysis.

5. Pharmacological properties
Pharmacotherapeutic group: Proton Pump Inhibitor.
ATC Code: A02BC06

5.1 Pharmacodynamic properties
Dexlansoprazole is a proton pump inhibitor (PPI) and is included in the drug class of antisecretory compounds. It blocks the final step of gastric acid secretion by specific inhibition of the (H+, K+)-ATPase at the secretory surface of the parietal cells on gastric mucosa.
Dexlansoprazole inhibits the H/K ATPase enzyme, which is involved in the secretion of hydrochloric acid, hydrolyzing ATP and exchanging H+ ions from the cytoplasm for K+ ions in the secretory canaliculus, which results in HCl secretion into the gastric lumen. Dexlansoprazole inhibits this effect of H/K ATPase by demonstrating a high degree of activation in the acidic environment. After passing through the liver and reaching the gastric parietal cells activated by a meal, PPIs undergo protonation in the acidic pH environment, followed by conversion to sulphenamide which represents the active form of the drug. Sulphenamide inhibits the activity of the proton pump and hence the transport of hydrogen ions into the gastric lumen via covalent binding to the SH groups of the cysteine residues of H/K ATPase. The delivery technology of dexlansoprazole delayed release capsule is designed to release the drug in two separate pH-dependent phases, the first in the proximal duodenum (25% of total drug dose) and the second (75% of total drug dose) in the more distal small intestine. Dexlansoprazole reduces both basal and stimulated gastric acid secretion.

5.2 Pharmacokinetic properties
The dual delayed release formulation of dexlansoprazole delayed release capsules 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.

Absorption
After oral administration of Dexlansoprazole delayed release capsules 30 mg or 60 mg to healthy subjects, mean C_{max} and AUC values of dexlansoprazole increased approximately dose proportionally.

Distribution
Plasma protein binding of dexlansoprazole ranged from 96.1% to 98.8% in healthy subjects and was independent of concentration from 0.01 to 20 mcg/mL. The apparent volume of distribution (V_z/F) after multiple doses in symptomatic GERD patients was 40.3 L.

Metabolism
Dexlansoprazole is extensively metabolized in the liver by oxidation, reduction, and subsequent formation of sulfate, glucuronide and glutathione conjugates to inactive metabolites. Oxidative metabolites are formed by the cytochrome P450 (CYP) enzyme system including hydroxylation mainly by CYP2C19, and oxidation to the sulfone by CYP3A4. Dexlansoprazole is the major circulating component in plasma regardless of CYP2C19 metabolizer status. In CYP2C19 intermediate and extensive metabolizers, the major plasma metabolites are 5-hydroxy dexlansoprazole and its glucuronide conjugate, while in CYP2C19 poor metabolizers dexlansoprazole sulfone is the major plasma metabolite.

Elimination
Dexlansoprazole is eliminated with a half-life of approximately one to two hours in healthy subjects and in patients with symptomatic GERD. No accumulation of dexlansoprazole occurs after multiple, once daily doses of Dexlansoprazole delayed release capsules 30 mg or 60 mg, although mean AUC and Cmax values of dexlansoprazole were slightly higher (less than 10%) on day 5 than on day 1.
Dexlansoprazole is cleared from the body by either fecal excretion (50.7%) or renal excretion (47.6%) following oral ingestion, with no unchanged drug detected in the urine.

5.3 Preclinical safety data
None available

6. Pharmaceutical particulars
6.1 List of Excipients:
- Hard gelatin capsule

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store below 30°C, Protect from direct sunlight, heat & moisture.

6.5 Nature and contents of container
Lanspure® DR 30 is available as 1x10 Capsules in Alu-Alu Blister pack.

6.6 Special precautions for disposal and other handling
Any unused medicine product or waste material should be disposed of in accordance with the local requirements.

7. Marketing authorization holder and manufacturing site addresses
Manufactured in India by:
RELAX BIOTECH PVT. LTD.
862/1, GIDC, Makarpura,
Vadodara – 390010,
Gujarat, India.

Manufactured for & Marketed by:
KRISHNA CHEMISTS LTD.
P.O. BOX 3328-00506
NAIROBI, KENYA.

8. Marketing Authorization Number
H2020/CTD5423/1750ER

9. Date of first authorization/renewal of the authorization

23/07/2026

10. Date of revision of the text
23/07/2026