Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

DEXRABEPRAZOLE SODIUM TABLETS 10 MG

2. Qualitative and quantitative composition

Each enteric-coated tablet contains:
Dexrabeprazole Sodium……10 mg

Full list of excipients in Section 6.1.

3. Pharmaceutical form

Enteric-coated tablet
White coloured, round shape, biconvex, both sides plain enteric coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

Dexrabeprazole Sodium is indicated for Gastro esophageal reflux disease, gastric and duodenal ulcers.

4.2 Posology and method of administration

Posology

Adults
The usual dosage in adults is 10mg once daily in the morning for 4-8 weeks depending upon response of patient.
Maintenance of healing of GERD may suffice with a lower dose of 5 mg once daily.

Use in special population

Renal impairment
Caution may be necessary for patients with renal impairment, basis the clinical condition.

Hepatic impairment
Caution may be necessary for patients with hepatic impairment, basis the clinical condition.

Elderly
Basis the decreased hepatic, renal and cardiac function in elderly patients, caution may be required before giving Dexrabeprazole sodium tablets.

Children
The safety and effectiveness of dexrabeprazole in pediatric patients has not been established.

Method of administration
Dexrabeprazole Sodium tablets should not be chewed or crushed, but should be swallowed whole.

4.3 Contraindications

Dexrabeprazole sodium tablets is contraindicated in patients with known hypersensitivity to dexrabeprazole sodium, substituted benzimidazole or to any component of the formulation.
- Dexrabeprazole is contraindicated in pregnancy and during breast-feeding.

4.4 Special warnings and precautions for use

The special warnings and precautions with rabeprazole shall also be applicable for dexrabeprazole and the same has been discussed below:
Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric or oesophageal malignancy, therefore the possibility of malignancy should be excluded prior to commencing treatment with rabeprazole sodium.
Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.
A risk of cross-hypersensitivity reactions with other proton pump inhibitor (PPI) or substituted benzimidazoles cannot be excluded.
There have been post marketing reports of blood dyscrasias (thrombocytopenia and neutropenia). In the majority of cases where an alternative aetiology cannot be identified, the events were uncomplicated and resolved on discontinuation of rabeprazole.
Hepatic enzyme abnormalities have been seen in clinical trials and have also been reported. In the majority of cases where an alternative aetiology cannot be identified, the events were uncomplicated and resolved on discontinuation of rabeprazole.
No evidence of significant drug related safety problems was seen in a study of patients with mild to moderate hepatic impairment versus normal age and sex matched controls. However, because there are no clinical data on the use of rabeprazole in the treatment of patients with severe hepatic dysfunction, the prescriber is advised to exercise caution when treatment with rabeprazole is first initiated in such patients.

Co-administration of atazanavir with rabeprazole is not recommended.
Treatment with PPIs, including rabeprazole sodium, may possibly increase the risk of gastrointestinal infections such as Salmonella, Campylobacter and Clostridium difficle. PPIs, especially if used in high

doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in older people or in presence of other recognised risk factors. Observational studies suggest that PPIs may increase the overall risk of fracture by 10-40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.
Severe hypomagnesemia, has been reported in patients treated with PPIs like rabeprazole sodium for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesemia improved after magnesium replacement and discontinuation of the PPI.
For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g. diuretics), healthcare professionals should consider measuring magnesium levels prior to initiation of PPI treatment and periodically during treatment.

Concomitant use of rabeprazole 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. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.

Influence on vitamin B12 absorption:
All acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or a- chlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy or if respective clinical symptoms are observed.

Subacute cutaneous lupus erythematosus (SCLE):
PPIs are associated with very infrequent cases of SCLE. If lesions occur, especially in unexposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping rabeprazole sodium. SCLE after previous treatment with a PPI may increase the risk of SCLE with other PPIs.

Interference with laboratory tests:
Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, rabeprazole sodium treatment should be stopped for at least 5 days before CgA measurements. If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of PPI treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Dexrabeprazole does not have clinically significant interactions with drugs metabolized through CYP450 like warfarin, theophylline, diazepam and phenytoin.
The drug interactions with rabeprazole shall also be applicable for dexrabeprazole and the same has been discussed below:
Rabeprazole sodium produces a profound and long-lasting inhibition of gastric acid secretion. An interaction with compounds whose absorption is pH dependent may occur. Co-administration of rabeprazole sodium with ketoconazole or itraconazole may result in a significant decrease in antifungal plasma levels. Therefore, individual patients may need to be monitored to determine if a dosage adjustment is necessary when ketoconazole or itraconazole are taken concomitantly with rabeprazole.
In clinical trials, antacids were used concomitantly with the administration of rabeprazole and, in a specific drug-drug interaction study, no interaction with liquid antacids was observed.
Co-administration of atazanavir 300 mg/ritonavir 100 mg with omeprazole (40 mg once daily) or atazanavir 400 mg with lansoprazole (60 mg once daily) to healthy volunteers resulted in a substantial reduction in atazanavir exposure. The absorption of atazanavir is pH dependent.
Although not studied, similar results are expected with other PPIs. Therefore, PPIs including rabeprazole, should not be co- administered with atazanavir.
Studies in healthy subjects have shown that rabeprazole sodium does not have clinically significant interactions with amoxicillin. Rabeprazole does not adversely influence plasma concentrations of amoxicillin or clarithromycin when co-administered for the purpose of eradicating upper gastrointestinal A. pylori infection.
No interaction is expected between rabeprazole and cyclosporin.

Methotrexate
Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of PPIs and methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxy methotrexate. However, no formal drug interaction studies of methotrexate with PPIs have been conducted.

4.6 Pregnancy and Lactation

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Dexrabeprazole is contraindicated during pregnancy.

Lactation
There are no studies in lactating women and it is not known whether dexrabeprazole sodium is excreted in breast milk. Therefore, dexrabeprazole should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Based on the pharmacodynamic properties and the adverse events profile, it is unlikely that rabeprazole would cause an impairment of driving performance or compromise the ability to use machinery. If, however, alertness is impaired due to somnolence, it is recommended that driving and operating complex machinery be avoided.

4.8 Undesirable effects

Dexrabeprazole was well tolerated during clinical trials. Adverse effects reported during post marketing study were: headache, diarrhea, nausea, malaise, skin eruptions, dizziness, itching,
dryness of mouth, dryness of skin, drowsiness, fatigue, constipation, abdominal fullness, arthralgias, vomiting, loss of appetite, breathlessness. The adverse events with rabeprazole shall also be applicable for dexrabeprazole and the same has been discussed below:
The most commonly reported adverse drug reactions, during controlled clinical trials with rabeprazole were headache, diarrhoea, abdominal pain, asthenia, flatulence, rash and dry mouth.
The majority of adverse events experienced during clinical studies were mild or moderate in severity, and transient in nature.
The following adverse events have been reported from clinical trial and post-marketing experience.
Frequencies are defined as: Common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

System organ class	**Frequency**	**Adverse reactions**
Infections and infestations	Common	Infection
Blood and lymphatic system disorders	Rare	Neutropenia Leucopenia Thrombocytopenia Leukocytosis
Immune system disorders	Rare	Anorexia

	Not Known	Hyponatremia Hypomagnesaemia
Psychiatric disorders	Common	Insomnia
	Uncommon	Nervousness
	Rare	Depression
	Not Known	Confusion
Nervous system disorders	Common	headache, dizziness
	Uncommon	Somnolence
Eye disorders	Rare	Visual disturbance
Vascular disorders	Not Known	Peripheral Oedema
Respiratory, thoracic and mediastinal disorders	Common	Cough Pharyngitis Rhinitis
	Uncommon	Bronchitis Sinusitis
Gastrointestinal disorders	Common	Diarrhoea Vomiting Nausea
	Uncommon	Abdominal pain Constipation Flatulence Fundic gland polyps (Benign)
	Rare	Gastritis Stomatitis Taste Disturbance
	Not Known	Microscopic Colitis
Hepatobiliary disorders	Rare	Hepatitis Jaundice Hepatic encephalopathy
Skin and subcutaneous tissue disorders	Uncommon	Rash Erythema
	Rare	Pruritus Sweating Bullous reactions

	Very Rare	Erythema multiforme, toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS)
	Not known	Subacute cutaneous lupus erythematosus
Musculoskeletal connective tissue and bone disorders	Common	Non-specific pain Back Pain
	Uncommon	Myalgia Leg cramps Arthralgia Fracture of the hip, wrist or spine
Renal and urinary disorders	Uncommon	Urinary tract infection
	Rare	Interstitial nephritis
Reproductive system and breast disorders	Not Known	Gynecomastia
General disorders and administration site conditions	Common	Asthenia Influenza like illness
	Uncommon	Chest pain Chills Pyrexia
Investigations	Uncommon	Increased hepatic enzymes
	Rare	Weight increased

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions: 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 has been no experience with large overdoses with dexrabeprazole sodium tablets. Experience to date with deliberate or accidental overdose is limited. The maximum established exposure has not exceeded 60 mg twice daily, or 160 mg once daily. Effects are generally minimal, representative of the known adverse event profile and reversible without further medical intervention. No specific antidote is known. Rabeprazole sodium is extensively protein bound and is, therefore, not dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

5. Pharmacological properties

Pharmacotherapeutic group: Proton Pump Inhibitor
ATC-Code: A02BC07

5.1 Pharmacodynamic properties

Mechanism of action
Dexrabeprazole sodium belongs to the class of antisecretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H2 histamine antagonist properties, but suppress gastric acid secretion by the specific inhibition of the H+/K+- ATPase enzyme at the secretory surface of the gastric parietal cell. This enzyme system is regarded as the acid (proton) pump, and therefore Dexrabeprazole sodium is classified as a gastric proton- pump inhibitor blocking the final step of acid production. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. Animal studies indicate that after administration, dexrabeprazole sodium rapidly disappears from both the plasma and gastric mucosa.

Pharmacodynamic effects:
DEXRABEPRAZOLE SODIUM TABLETS indicated for Gastro esophageal reflux disease, gastric and duodenal ulcers

5.2 Pharmacokinetic properties

Absorption:
Oral bioavailability: about 52% and peak plasma concentrations are reached about 3.5 hr. after oral admin.
Distribution:
Protein-binding: 97%.
Metabolism:
Extensively metabolised in the liver by cytochrome P450 isoenzymes.
Excretion:
Metabolites are mainly excreted in the urine (90%).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. No carcinogenicity studies have been performed; however, there is no evidence to suggest carcinogenic potential.

6. Pharmaceutical Particulars

6.1 List of Excipients

Calcium carbonate
Colloidal Silicon Dioxide
Cross Povidone
Mannitol
Hypromellose E15

Talc
Magnesium Stearate
Dibasic Calcium Phosphate
Enrobage + Moistshied (EP-MS-110) White
Av coat EC
Isopropyl Alcohol
Methylene dichloride

6.2 Incompatibilities

None

6.3 Shelf-Life

24 Months

6.4 Special Precautions for storage

Store in a dry & dark place at a temperature below 30˚C.

6.5 Nature and Content of container

10 Tablets packed in one Alu-Alu blister Pack
03 Alu-Alu blister to be pack in carton along with Insert.

6.6 Special precautions for disposal and other handling

No Special Requirements.

7. Marketing Authorization Holder
Hiral Labs Ltd
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8. Marketing Authorization Number
H2016/CTD251/559/R1

9. Date of first authorization/renewal of the authorization
02 September 2026

10. Date of revision of the text

02 September 2026