National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

DEXRABEPRAZOLE SODIUM TABLETS 10MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each enteric- coated tablet contains:

Dexrabeprazole sodium	10 mg
Excipients	Q.S

Colour: Titanium Dioxide BP

3. PHARMACEUTICAL FORM

Oral Enteric coated tablets

4. Clinical particulars

4.1 Therapeutic indications

DEXRABEPRAZOLE SODIUM TABLETS indicated for Gastro esophageal reflux disease, gastric and duodenal ulcers.

4.2 Posology and method ofadministration

DEXRABEPRAZOLE SODIUM TABLETS are depending upon the clinical requirements in individual cases, the following daily doses are recommended:

Adults - 10 mg once daily for 4-8 weeks depending upon condition and response.

Maintenance – 5 -10 mg once daily.

4.3 Contraindications

Hypersensitivity to Dexrabeprazole Sodium

4.4 Special warnings and precautions for use

General- Symptomatic response to therapy does not preclude the presence of gastric malignancy.

Drug interaction- No clinically significant interactions with drugs metabolized by CYP450 system. An interaction with compounds (e.g Ketoconazole) which are dependent on gastric pH for absorption may occour due to the magnitude of acid suppression.

4.5 Interaction with other medicinal products and other forms of interaction

May reduce absorption of ketoconazole and itraconazole. May prolong the elimination of diazepam, phenytoin and warfarin.

4.6 Pregnancy and Lactation

Pregnancy

Studies in animals have shown no risk to the fetus, however there are no sufficient studies in humans. Patients should follow the advice of the doctor regarding its use. Patients should follow the advice of the doctor regarding its use.

Lactation

Safer: Drug has been studied in few breastfeeding women and the evidence shows that there is no increase in side effects in the infants, or the possibility of harm to the breastfed infants is expected to

be rare. Patients should follow the advice of the doctor regarding its use.

4.7 Effects on ability to drive and use machines

There are no data to suggest that Dexrabeprazole affects the ability to drive or use machines.

4.8 Undesirable effects

Headache, Diarrhea, Nervousness, Abdominal Pain, Pharyngitis, rash and dry mouth.

4.9 Overdose

Any medication taken in excess can have serious consequences. If you suspect an overdose of Dexrabeprazole Sodium, seek medical attention immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group:Proton Pump Inhibitor

ATC code: A02BC07

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

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light magnesium Oxide

Mannitol

Hypromellose

Povidone

Acetone

Croscarmellose Sodium

Magnesium Stearate

Colorezy White Seal Coat

Isopropyl alcohol

Methylene Chloride

Enteric Coat White

Colour Titanium dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months for the date of manufacturing.

6.4 Special precautions for storage

Store below 30º C. Protect from light. Keep out of reach of children

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

2x14 Tablets in Alu PVC blister pack

6.6 Special precautions for disposal <and other handling>

There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

7. <APPLICANT/MANUFACTURER>

Stallion laboratories Pvt. Ltd.

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