SUMMARY PRODUCT CHARACTERISTICS(SPC)

1.NAME OF THE MEDICINAL PRODUCT

PENURA-DSR (Pantoprazole 40mg Gastro Resistant and Domperidone 30mg Sustained Release Capsules)

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains
Pantoprazole Sodium BP
Equivalent to Pantoprazole 40
mg (As enteric coated pellets)
Domperidone BP 30
mg (As sustained release pellets)

For full list of excipients, see section 6.1

3.PHARMACEUTICAL FORM

Oral Capsules
Size "2" black cap/orange body hard gelatin capsule containing blue and orange pellets
10 Capsules in Alu Alu Blister; 3 such blisters are packed in a carton along with Pack Insert

4.CLINICAL PARTICULARS

4.1 Therapeutic Indications

PENURA-DSR is indicated in the management of gastroesophageal reflux disease; gastritis, non-ulcer dyspepsia, gastric or duodenal ulcer, dyspepsia, bloating, fullness, belching, NSAID-induced dyspepsia.

4.2 Posology and Method of Administration

The usual recommended dose of Penura-DSR is one capsule daily before breakfast. The dosage should be as recommended by the Physician

4.3 Contraindications

Hypersensitivity to Pantoprazole Sodium, Domperidone or to any of the ingredients in the formulation.
Penura-DSR is contraindicated in Pregnancy and Lactation.

4.4 Special warnings and precautions for use

Penura-DSR should be given with caution to patients with renal dysfunction or hepatic dysfunction.
Because Domperidone is extensively metabolized, response to the drug should be carefully monitored in patients with hepatic impairment

4.5 Interactions with other medicinal products and other forms of interaction

Pantoprazole

Pantoprazole is metabolized through the cytochrome P450 system, primarily the CYP2C19 and CYP3A4 isoenzymes, and subsequently undergoes phase II conjugation. Based on studies evaluating possible interactions of Pantoprazole with other drugs metabolized by the cytochrome P450 system, no dosage adjustment is needed with concomitant use of the following drugs: theophylline, cisapride, antipyrine, caffeine, carbamezapine diazepam, diclofenac, digoxin, ethanol, glyburide, oral contraceptives (levonorgestrel / ethynylestradiol), metoprolol, nifedipine,

phenytoin or warfarin. Clinically relevant interactions of Pantoprazole with other drugs with the same metabolic pathways are not expected. Therefore, when co-administered with Pantoprazole, adjustment of the dosage of Pantoprazole with such drugs may not be necessary. There was also no interaction with concomitantly administered antacids. Because of profound and long lasting inhibition of gastric acid secretion, it is theoretically possible that Pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g. Ketoconazole, Ampicillin esters, and iron salts).

Domperidone
Anti-cholinergic drugs may inhibit the anti-dyspeptic effects of Domperidone. Antimuscarinic agents and opioid analgesics may antagonise the effect of Domperidone. Domperidone suppresses the peripheral effects (digestive disorders, nausea and vomiting) of dopaminergic agonists. Since Domperidone has gastrokinetic effects, it could influence the absorption of concomitant orally administered drugs, particularly those with sustained release or enteric coated formulations. As Domperidone interferes with serum prolactin levels, it may interfere with other hypoprolactinaemic agents and with some diagnostic tests. Antacids and anti-secretory agents lower the oral bioavailability of Domperidone. They should be taken after meals and not before meals, i.e. they should not be taken simultaneously with Domperidone. Reduced gastric acidity impairs the absorption of Domperidone. Oral bioavailability is decreased by prior administration of Cimetidine or Sodium Carbonate

4.6 Fertility, pregnancy, and lactation
Penura-DSR is contraindicated in Pregnancy and Lactation

4.7 Effect on ability to drive and machines
None known

4.8 Undesirable Effects
Pantoprazole the adverse reactions associated with Pantoprazole include Headache, Diarrhoea, Skin rash, Pruritus and Dizziness. Domperidone Serum prolactin level may rise resulting in galactorrhea in females and less frequently gynaecomastia in males due to Domperidone. Dry mouth, Thirst, Headache, Nervousness, Drowsiness, Diarrhoea, Skin rashes and Itching may follow treatment with Domperidone.

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 to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org/

4.9 Overdose

In the event of overdosage, gastric lavage should be performed. Symptomatic and supportive measures are recommended.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pantoprazole: Pantoprazole, a benzimidazole sulphoxide derived prodrug, is an irreversible proton pump inhibitor. Pantoprazole, being a weak base, is highly ionized at low pH and readily accumulated in the highly acidic canalicular lumen of the stimulated parietal cell in the stomach. In this acidic environment, it is protonated and rapidly converted to a cationic cyclic sulphonamide. The sulphonamide binds covalently to cysteine residues on the luminal (acidic) surface of H+ / K+-ATPase to form a mixed disulphide; thus causing irreversible inhibition of the gastric proton pump. This inhibition of the gastric proton pump or H+ / K+ - ATPase (which represents the final step in the secretory process), suppresses gastric acid secretion. Domperidone : Domperidone, a benzimidazole derivative (structurally related to the butyrophenones), acts by selectively antagonizing the peripheral dopaminergic D2 receptors in the gastrointestinal (G.I.) wall, thereby enhancing gastrointestinal peristalsis and motility and increasing Lower Esophageal Sphincter (LES) tone.

5.2 Pharmacokinetic Properties

Pantoprazole Pantoprazole is rapidly absorbed after oral administration, with peak plasma concentrations (Cmax) of 1.1 to 3.1. (mean 2.1) mg/L occurring within 2 to 4 (mean 2.7) hours (tmax) after ingestion of an enteric coated 40 mg tablet. The volume of distribution is low (mean 0.16 L/kg at steady state) due to high degree of plasma protein binding (~98%). Plasma Pantoprazole concentrations decline monophasically after oral administration, with a mean plasma terminal half-life (t½β) of 0.9 to 1.9 hours. However, since inhibition of acid secretion is noncompetitive or irreversible, there is no correlation between plasma levels and the duration of action of Pantoprazole. Concomitant intake of food has no influence on the bioavailability of Pantoprazole, and any possible retardant effect of food on the rate of drug absorption is not of clinical relevance, considering the prolonged antisecretory action of Pantoprazole. The enteric coating does not influence the bioavailability of Pantoprazole.2 Pantoprazole undergoes extensive hepatic metabolism via cytochrome P450 oxidase followed by sulphate conjugation. Elimination of Pantoprazole is PREDOMINANTLY RENAL, WITH ~80% OF AN ORAL DOSE BEING EXCRETED AS URINARY metabolite; the remainder is excreted in the faeces and originates primary from biliary secretion. Domperidone Domperidone is rapidly and almost completely (93%) absorbed after oral administration. Peak plasma concentrations occur within 30 min. after oral administration. The peak plasma concentration value after a 20mg oral dose is in the range of 15 to 19 ng/ml. The mean elimination half life ranges from 12 - 16 hours for an oral dose. Oral

bioavailability of Domperidone is 13 - 17% because of extensive presystemic metabolism in gut wall and liver. Administration of Domperidone 90 minutes after a meal increases bioavailability whereas Cimetidine or alkali pretreatment reduces bioavailability. Domperidone is strongly bound to plasma proteins (90-93%). Domperidone undergoes extensive biotransformation with < 1% excreted unchanged in urine

5.3 Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6.PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Not Applicable

6.2 Incompatibilities

None known

6.3 Shelf Life

36 months

6.4 Special precautions for Storage

Store below 30°C. Protect from light.
Nature and Contents of Container
10 Capsules in printed Alu/Alu Blister and such 3 blisters are packed in a printed carton along with Pack Insert.

6.5 Special Precautions for disposal and other handling

Not applicable

7.0 MARKETING AUTHORIZATION HOLDER AND MANUFACTURING ADRESS

AURA LIFECARE PVT. LTD.
S.No: 254/14/1, Jarod - Savli Road, P.O.: Karachiya -
391520, Tal: Savli, Dist : Vadodara,
Gujarat, India.

8.0 MARKETING AUTHORIZATION NUMBER

H2024/CTD10976/23073

9.0 DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION

2024 September 16

10.0 DATE OF REVISION

2024 September 16