SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. Name of the medicinal product

PANTODOM (Pantoprazole & Domperidone Sustain Release Capsules)

2. Qualitative and quantitative composition

Label Claim:

Each hard gelatine capsule contains :
Pantoprazole sodium sequihydrate B.P
Eq. to pantoprazole (as enteric coated pellets).....40mg
Domperidone B.P (as enteric coated pellets).....30mg
Excipients.....q.s

3. Pharmaceutical form

Hard Gel Capsules
A Pink/CT Coloured, Size-2 hard gelatin capsule containing blue and orange coloured pellets.

4. Clinical particulars

4.1 Therapeutic indications

- Gastro-esophageal reflux disease(GERD)
- Erosive esophagitis
- Gastric and duodenal ulcers
- The relief of the symptoms of nausea and vomiting, epigastric sense of fullness, upper abdominal discomfort and regurgitation of gastric contents.

4.2 Posology and method of administration

Posology

Per capsule contains pantoprazole 40 mg and domperidone 30 mg: 1 capsule once daily.

4.3 Contraindications

Pantodom capsules are contraindicated in the following:

- In patients with a known hypersensitivity to pantoprazole or domperidone or any other inactive ingredients of the tablets.
- Prolactin-releasing pituitary tumour (prolactinoma).
- When stimulation of the gastric motility could be harmful: gastrointestinal haemorrhage, mechanical obstruction or perforation.
- Hepatic and/or renal impairment.

4.4 Special warnings and precautions for use

PANTOPRAZOLE

Concurrent Gastric Malignancy

Symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy.

Atrophic Gastritis

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with pantoprazole, particularly in patients who were Helicobacter pylori positive.

Cyanocobalamin (Vitamin B12) Deficiency

Generally, daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (Vitamin B12) caused by hypo- or achlorhydria. Rare reports of cyanocobalamin deficiency occurring with acidsuppressing therapy have been reported in the literature. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.

Bon 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.

Hypomagnesaemia

Hypomagnesaemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least 3 months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias and seizures. In most patients, treatment of hypomagnesaemia required magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), healthcare professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.

Tumourigenicity

Due to the chronic nature of GERD, there may be a potential for prolonged administration of pantoprazole. In long-term rodent studies, pantoprazole was carcinogenic and caused rare types of gastrointestinal tumours. The relevance of these findings to tumour development in humans is unknown.

Long-term Treatment

In long-term treatment, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

Gastrointestinal Infections Caused by Bacteria

Pantoprazole, like all PPIs, might be expected to increase the counts of bacteria normally present in the upper gastrointestinal tract. Treatment with pantoprazole may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as Salmonella and Campylobacter.

DOMPERIDONE

Patients who find they have post-prandial symptoms that persist, and are having to take domperidone continuously for more than 2 weeks should consult their doctor. Patients who find that their nausea and vomiting persists for more than 48 hours should consult their doctor. Domperidone is not recommended for the treatment of motion sickness. Domperidone

is also not recommended for use in patients with underlying cardiac disease without medical supervision.
These tablets contain lactose and may be unsuitable for patients with lactose intolerance, galactosaemia or glucose/galactose malabsorption.

Use with Potent CYP3A4 Inhibitors

Co-administration with oral ketoconazole, erythromycin or other potent CYP3A4 inhibitors that prolong the QTc interval should be avoided.

Cardiac Effects

Some epidemiological studies showed that domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. The risk may be higher in patients older than 60 years and at daily doses of more than 30 mg. Domperidone should be used at the lowest effective dose in adults and children.
Use of domperidone and other drugs which prolong QTc intervals requires that caution be exercised in patients who have existing prolongation of cardiac conduction intervals, particularly the QTc, and in patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure.

4.5 Interaction with other medicinal products and other forms of interaction

Tell your doctor what other medications you are taking or using, this includes all prescription, over-the-counter, and herbal remedies, to avoid a drug interaction.
Do not take Pantadom if you take medications such as

- HIV/AIDS medications
- Ketoconazole or erythromycin

If you take warfarin or coumadin, Pantadom can intensify their affect causing bleeding. This is not a complete list of drugs that may interact with Pantadom. Ask your doctor or pharmacist for a complete list.

4.6 Fertility, pregnancy and lactation

PANTOPRAZOLE

Pregnancy Category B (Fertility and pregnancy)

Reproduction studies have been performed in rats at oral doses up to 88 times the recommended human dose and in rabbits at oral doses up to 16 times the recommended human dose and have revealed no evidence of impaired fertility or harm to the foetus due to pantoprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

DOMPERIDONE

There are limited post-marketing data on the use of domperidone in pregnant women. Studies in animals have shown reproductive toxicity at maternally toxic doses. Domperidone should only be used during pregnancy when justified by the anticipated therapeutic benefit.

Lactation:

PANTOPRAZOLE

Pantoprazole and its metabolites are excreted in the milk of rats. Pantoprazole excretion in human milk has been detected in a study of a single nursing mother after a single 40 mg oral dose. The clinical relevance of this finding is not known. Many drugs that are excreted in human milk have a potential for serious adverse reactions in nursing infants. Based on the potential for tumourigenicity shown for pantoprazole in rodent carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

DOMPERIDONE

Domperidone concentrations in breast milk of lactating women are 10 to 50% of the corresponding plasma concentrations and expected not to exceed 10ng/ml. The total amount of domperidone excreted in human breast milk is expected to be less than 7µg per day at the highest recommended dosing regimen. It is not known whether this is harmful to the newborn. Therefore breast-feeding is not recommended for mothers who are taking domperidone.

4.7 Effects on ability to drive and use machines

Pantoprazole has no or negligible influence on the ability to drive and use machines.Adverse drug reactions such as dizziness and visual disturbances may occur (see section 4.8). If affected, patients should not drive or operate machines.

Domperidone has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

PANTOPRAZOLE

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adults

Safety in nine randomized comparative US clinical trials in patients with GERD included 1,473 patients on oral pantoprazole (20 mg or 40 mg), 299 patients on an H_2-receptor antagonist, 46 patients on another PPI, and 82 patients on placebo. The most frequently occurring adverse reactions are listed in Table 1.

Table 1: Adverse Reactions Reported in Clinical Trials of Adult Patients with GERD at a Frequency of >2%:

	Pantoprazole(n=1,473)%	Comparators(n=345)%	Placebo(n=82)%
Headache	12.2	12.8	8.5
Diarrhoea	8.8	9.6	4.9
Nausea	7.0	5.2	9.8
Abdominal pain	6.2	4.1	6.1
Vomiting	4.3	3.5	2.4
Flatulence	3.9	2.9	3.7
Dizziness	3.0	2.9	1.2
Arthralgia	2.8	1.4	1.2

Additional adverse reactions that were reported for pantoprazole in clinical trials with a frequency of ≤2% are listed below by body system:

Body as a Whole
Allergic reaction, pyrexia, photosensitivity reaction, facial oedema.

General Disorders at Site of Administration
Asthenia, fatigue and malaise, body temperature increased; oedema peripheral

Gastrointestinal
Diarrhoea; nausea/vomiting; abdominal distension and bloating; constipation; dry mouth; abdominal pain and discomfort, hepatitis.

Haematologic
Leucopenia, thrombocytopenia

Metabolic/Nutritional
Elevated creatine kinase, generalized oedema, elevated triglycerides, liver enzymes (transaminases, gamma-GT) and bilirubin elevated, weight changes.

Musculoskeletal
Fracture of the hip, wrist or spine,myalgia, athralgia.

Nervous
Depression (and all aggravations), vertigo.

Skin and Appendages

Rash/exanthema/eruption, urticaria, pruritus, angio-oedema.

Special Senses

Disturbances in vision/blurred vision.

Reproductive System and Breast Disorders

Gynaecomastia.

Paediatric Patients

Safety of pantoprazole in the treatment of erosive esophagitis (EE) associated with GERD was evaluated in paediatric patients aged 1 year through 16 years in three clinical trials. Safety trials involved paediatric patients with EE; however, as EE is uncommon in the paediatric population, 249 paediatric patients with endoscopically-proven or symptomatic GERD were also evaluated. All adult adverse reactions to pantoprazole are considered relevant to paediatric patients. In patients aged 1 year through 16 years, the most commonly reported (>4%) adverse reactions include URI, headache, fever, diarrhoea, vomiting, rash, and abdominal pain.

Additional adverse reactions that were reported for pantoprazole in paediatric patients in clinical trials with a frequency of ≤4% are listed below by body system:

Body as a Whole

Allergic reaction, facial oedema.

Gastrointestinal
Constipation, flatulence, nausea.

Metabolic/Nutritional
Elevated triglycerides, elevated liver enzymes, elevated creatine kinase.

Musculoskeletal
Arthralgia, myalgia.

Nervous
Dizziness, vertigo.

Skin and Appendages
Urticaria.

The following adverse reactions seen in adults in clinical trials were not reported in paediatric patients in clinical trials, but are considered relevant to paediatric patients: photosensitivity reaction, dry mouth, hepatitis, thrombocytopenia, generalized oedema, depression, pruritus, leucopenia, and blurred vision.

Zollinger-Ellison Syndrome
In clinical studies of Zollinger-Ellison syndrome, adverse reactions reported in 35 patients taking pantoprazole 80 mg/day to 240 mg/day for up to 2 years were similar to those reported in adult patients with GERD.

Postmarketing Experience
The following adverse reactions have been identified during post-approval use of pantoprazole. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

These adverse reactions are listed below by body system:
General Disorders and Administration Conditions: Asthenia, fatigue, malaise.
Hepatobiliary Disorders: Hepatocellular damage, leading to jaundice and hepatic failure.
Immune System Disorders: Anaphylaxis (including anaphylactic shock).
Investigations: Weight changes.

Metabolism and Nutritional Disorders: Hyponatraemia, hypomagnesaemia.
Musculoskeletal Disorders: Rhabdomyolysis, bone fracture.
Psychiatric Disorders: Hallucination, confusion, insomnia, somnolence.
Renal and Urinary Disorders: Interstitial nephritis.
Skin and Subcutaneous Tissue Disorders: Severe dermatologic reactions (some fatal), including erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis (some fatal), and angio-oedema (Quincke's oedema).

DOMPERIDONE

The safety of domperidone was evaluated in 1,275 patients with dyspepsia, GERD, irritable bowel syndrome (IBS), nausea and vomiting or other related conditions in 31 double-blind, placebo-controlled studies.

Studies in diabetic gastroparesis or symptoms secondary to chemotherapy or Parkinsonism were excluded. The following terms and frequencies are applied: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), and very rare (<1/10,000).

Where frequency cannot be estimated from clinical trials data, it is recorded as "Not known".

Table 3:

System Organ Class	**Adverse Drug Reaction Frequency**	
	Common	**Uncommon**
Psychiatric Disorders		Loss of libido Anxiety
Nervous System Disorders		Somnolence Headache
Gastrointestinal Disorders	Dry mouth	Diarrhoea
Skin and Subcutaneous Tissue Disorder		Rash Pruritus
Reproductive System and Breast Disorders		Galactorrhoea Breast pain Breast tenderness
General Disorders and Administration Site Conditions		Asthenia

Postmarketing Experience

In addition to the adverse effects reported during clinical studies and listed above, the following adverse drug reactions have been reported.

Table 3:

Immune System Disorders	
Not known	Anaphylactic reaction (including anaphylactic shock)
Psychiatric Disorders	
Not known	Agitation, nervousness
Nervous System Disorders	
Not known	Convulsion, extra-pyramidal disorder
Eye Disorders	
Not known	Oculogyric crisis
Cardiac Disorders	
Not known	Ventricular arrhythmias, sudden cardiac death, QTc prolongation
Skin and Subcutaneous Tissue Disorders	
Not known	Urticaria, angio-oedema
Renal and Urinary Disorders	
Not known	Urinary retention
Reproductive System and Breast Disorders	
Not known	Gynaecomastia, amenorrhoea
Investigations	
Not known	Liver function test abnormal, blood prolactin increased

Extra-pyramidal disorder occurs primarily in neonates and infants.

Other central nervous system-related effects of convulsion and agitation also are primarily reported in infants and children.

4.9 Overdose

Pantoprazole

Experience in patients taking very high doses of pantoprazole (>240 mg) is limited. Spontaneous postmarketing reports of overdose are generally within the known safety profile of pantoprazole.

Pantoprazole is not removed by haemodialysis. In case of overdosage, treatment should be symptomatic and supportive.

Single oral doses of pantoprazole at 709 mg/kg, 798 mg/kg and 887 mg/kg were lethal to mice, rats and dogs, respectively. The symptoms of acute toxicity were hypoactivity, ataxia, hunched sitting, limb-splay, lateral position, segregation, absence of ear reflex, and tremor.

Domperidone

Symptoms: Overdose has been reported primarily in infants and children. Symptoms of overdosage may include agitation, altered consciousness, convulsion, disorientation, somnolence and extra-pyramidal reactions.

Treatment: There is no specific antidote to domperidone; but, in the event of overdose, gastric lavage as well as the administration of activated charcoal may be useful. Close medical supervision and supportive therapy are recommended. Anticholinergic, anti-Parkinson drugs may be helpful in controlling the extra-pyramidal reactions.

5. Pharmacological properties

5.1 Pharmacodynamic properties

PANTOPRAZOLE

Mechanism of Action

Pantoprazole is a substituted benzimidazole, which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells.

Pantoprazole is converted to its active form in the acidic environment in the parietal cells where it inhibits the H^+,K^+-ATPase enzyme, i.e., the final stage in the production of hydrochloric acid in the stomach. The inhibition is dose-dependent and affects both basal and stimulated acid secretion. In most patients, freedom from symptoms is achieved within 2 weeks. As with other proton-pump inhibitors (PPIs) and H_2-receptor inhibitors, treatment with pantoprazole reduces acidity in the stomach and thereby increases gastrin in proportion to the reduction in acidity. The increase in gastrin is reversible. Since pantoprazole binds to the enzyme distal to the cell receptor level, it can inhibit hydrochloric acid secretion independently of the stimulation by other substances (acetylcholine, histamine, and gastrin).

Pantoprazole has the same effect whether administered orally or intravenously.

The fasting gastrin values increase under pantoprazole. In short-term use, in most cases, they do not exceed the upper limit of normal. During long-term treatment, gastrin levels double in most cases. An excessive increase, however, occurs only in isolated cases. As a result, a mild-to-moderate increase in the number of specific endocrine (ECL) cells in the stomach is observed in a minority of cases during long-term treatment (simple to adenomatoid hyperplasia). However, according to the studies conducted so far, the formation of carcinoid

precursors (atypical hyperplasia) or gastric carcinoids as were found in animal experiments have not been observed in humans.
An influence of a long-term treatment with pantoprazole exceeding 1 year cannot be completely ruled out on endocrine parameters of the thyroid, according to results in animal studies.

DOMPERIDONE

Mechanism of Action

Domperidone is a dopamine antagonist with anti-emetic properties. Domperidone does not readily cross the blood-brain barrier. In domperidone users, especially adults, extra-pyramidal side effects are very rare, but domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema. Animal studies, together with the low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on dopamine receptors.
Studies in humans have shown oral domperidone to increase lower oesophageal pressure, improve antroduodenal motility and accelerate gastric emptying. There is no effect on gastric secretion.

5.2 Pharmacokinetic properties

PANTOPRAZOLE

Absorption

Pantoprazole is rapidly absorbed and the maximal plasma concentration is achieved even after one single 40 mg oral dose. On average at about 2.5 h p.a. the maximum serum concentrations of about 2 - 3 µg/ml are achieved, and these values remain constant after multiple administration. Pharmacokinetics do not vary after single or repeated administration. In the dose range of 10 to 80 mg, the plasma kinetics of pantoprazole are linear after both oral and intravenous administration. The absolute bioavailability from the tablet was found to be about 77 %. Concomitant intake of food had no influence on AUC, maximum serum concentration and thus bioavailability. Only the variability of the lag-time will be increased by concomitant food intake.

Distribution

Pantoprazole's serum protein binding is about 98 %. Volume of distribution is about 0.15 l/kg.

Biotransformation

The substance is almost exclusively metabolized in the liver. The main metabolic pathway is demethylation by CYP2C19 with subsequent sulphate conjugation, other metabolic pathways include oxidation by CYP3A4.

Elimination

Terminal half-life is about 1 hour and clearance is about 0.1 l/h/kg. There were a few cases of subjects with delayed elimination. Because of the specific binding of pantoprazole to the

proton pumps of the parietal cell the elimination half-life does not correlate with the much longer duration of action (inhibition of acid secretion).
Renal elimination represents the major route of excretion (about 80 %) for the metabolites of pantoprazole, the rest is excreted with the faeces.

DOMPERIDONE

Absorption

Domperidone is rapidly absorbed after oral administration, with peak plasma concentrations occurring at approximately 1 hr after dosing. The Cmax and AUC values of domperidone increased proportionally with dose in the 10 mg to 20 mg dose range. A 2- to 3-fold accumulation of domperidone AUC was observed with repeated four times daily (every 5 hr) dosing of domperidone for 4 days.
The low absolute bioavailability of oral domperidone (approximately 15%) is due to an extensive first-pass metabolism in the gut wall and liver. Although domperidone's bioavailability is enhanced in normal subjects when taken after a meal, patients with gastro-intestinal complaints should take domperidone 15-30 minutes before a meal. Reduced gastric acidity impairs the absorption of domperidone. Oral bioavailability is decreased by prior concomitant administration of cimetidine and sodium bicarbonate. The time of peak absorption is slightly delayed and the AUC somewhat increased when the oral drug is taken after a meal.

Distribution

Oral domperidone does not appear to accumulate or induce its own metabolism; a peak plasma level after 90 minutes of 21 ng/ml after two weeks oral administration of 30 mg per day was almost the same as that of 18 ng/ml after the first dose. Domperidone is 91-93% bound to plasma proteins. Distribution studies with radiolabelled drug in animals have shown wide tissue distribution, but low brain concentration. Small amounts of drug cross the placenta in rats.

Biotransformation

Domperidone undergoes rapid and extensive hepatic metabolism by hydroxylation and N-dealkylation. In vitro metabolism experiments with diagnostic inhibitors revealed that CYP3A4 is a major form of cytochrome P-450 involved in the N-dealkylation of domperidone, whereas CYP3A4, CYP1A2 and CYP2E1 are involved in domperidone aromatic hydroxylation.

Excretion

Urinary and faecal excretions amount to 31 and 66% of the oral dose respectively.

5.3 Preclinical safety data

PANTOPRAZOLE:

Non-clinical data reveal no special hazard to humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity.
In the two-year carcinogenicity studies in rats neuroendocrine neoplasms were found. In addition, squamous cell papillomas were found in the forestomach of rats. The mechanism leading to the formation of gastric carcinoids by substituted benzimidazoles has been carefully investigated and allows the conclusion that it is a secondary reaction to the

massively elevated serum gastrin levels occurring in the rat during chronic high-dose treatment. In the two-year rodent studies an increased number of liver tumours was observed in rats and in female mice and was interpreted as being due to pantoprazole's high metabolic rate in the liver.
A slight increase of neoplastic changes of the thyroid was observed in the group of rats receiving the highest dose (200 mg/kg). The occurrence of these neoplasms is associated with the pantoprazole-induced changes in the breakdown of thyroxine in the rat liver. As the therapeutic dose in man is low, no harmful effects on the thyroid glands are expected.
In animal reproduction studies, signs of slight foetotoxicity were observed at doses above 5 mg/kg. Investigations revealed no evidence of impaired fertility or teratogenic effects.
Penetration of the placenta was investigated in the rat and was found to increase with advanced gestation. As a result, concentration of pantoprazole in the foetus is increased shortly before birth.

DOMPERIDONE:

Electrophysiological in vitro and in vivo studies indicate an overall moderate risk of domperidone to prolong the QT interval in humans. In in vitro experiments on isolated cells transfected with hERG and on isolated guinea pig myocytes, exposure ratios ranged between 26- 47-fold, based on IC50 values inhibiting currents through IKr ion channels in comparison to the free plasma concentrations in humans after administration of the maximum daily dose of 10 mg administered 3 times a day. Safety margins for prolongation of action potential duration in in vitro experiments on isolated cardiac tissues exceeded the free plasma concentrations in humans at maximum daily dose (10 mg administered 3 times a day) by 45-fold. Safety margins in in vitro pro-arrhythmic models (isolated Langendorff perfused heart) exceeded the free plasma concentrations in humans at maximum daily dose (10 mg administered 3 times a day) by 9- up to 45-fold. In in vivo models the no effect levels for QTc prolongation in dogs and induction of arrhythmias in a rabbit model sensitized for torsade de pointes exceeded the free plasma concentrations in humans at maximum daily dose (10 mg administered 3 times a day) by more than 22-fold and 435-fold, respectively. In the anesthetized guinea pig model following slow intravenous infusions, there were no effects on QTc at total plasma concentrations of 45.4 ng/mL, which are 3-fold higher than the total plasma levels in humans at maximum daily dose (10 mg administered 3 times a day). The relevance of the latter study for humans following exposure to orally administered domperidone is uncertain.
In the presence of inhibition of the metabolism via CYP3A4 free plasma concentrations of domperidone can rise up to 3-fold.
At a high, maternally toxic dose (more than 40 times the recommended human dose), teratogenic effects were seen in the rat. No teratogenicity was observed in mice and rabbits.

6. Pharmaceutical particulars

6.1 Incompatibilities

Not applicable.

6.2 Shelf life
36 months

6.3 Special precautions for storage
Store at a temperature not exceeding 30^0C. Protect from light & moisture.

6.4 Nature and contents of container
Aluminium Aluminium packs
Pack sizes:
3x10 hard gelatine capsule

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

7. Marketing authorization holder

M/S.ACTIVITY PHARMACEUTICAL CO.LTD
No.34 Agip Road, Mile 4, Rumueme, Port Harcourt, Riverese State, Nigeria

8. Manufacturer:

M/S.CENTURION REMEDIES PVT LIMITED
Division of Centurion Laboratories, G-5,6 & F-19,
Industrial Estate Gorwa, City Vadodara, Gujarat, India

9. Last Revised on 10 July 2024.