PROFESSIONAL INFORMATION SCHEDULING

STATUS: S4 ☐

1. NAME OF THE MEDICINE

RAN-LANSOPRAZOLE 15 Capsules

RAN-LANSOPRAZOLE 30 Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

RAN-LANSOPRAZOLE 15

Each capsule contains:

Lansoprazole 15 mg

Contains sugar: Sucrose 80 mg

RAN-LANSOPRAZOLE 30

Each capsule contains:

Lansoprazole 30 mg

Contains sugar: Sucrose160 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule

RAN-LANSOPRAZOLE 15: Yellow cap/yellow body, self locked hard gelatin capsule of size '3' imprinted with 'L 15' on both cap and body containing white to off-white pellets.

RAN-LANSOPRAZOLE 30: Purple cap/lavender body, self locked hard gelatin capsule of size '1' imprinted with 'L 30' on both cap and body containing white to off-white pellets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RAN-LANSOPRAZOLE 30 is indicated for the short-term treatment of gastric and duodenal ulcers and reflux oesophagitis

RAN-LANSOPRAZOLE 15 is indicated in the short-term management of mild functional dyspepsia and for the prevention of relapse of gastro-oesophageal reflux.

RAN-LANSOPRAZOLE is indicated for *Helicobacter pylori*-positive duodenal ulcers in conjunction with appropriate antibiotics as part of an eradication programme.

4.2 Posology and method of administration

Posology

Gastric ulcer:

30 mg once a day for up to eight weeks.

Duodenal ulcer:

30 mg once a day for up to four weeks.

RAN-LANSOPRAZOLE is indicated for *Helicobacter pylori*-positive ulcers, as part of an eradication program with appropriate antibiotics.

Oesophagitis due to gastro-oesophageal Reflux:

30 mg once a day for four weeks. If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

Maintenance treatment for the prevention of gastro-oesophageal reflux:

15 mg once a day for a maximum period of one year.

Functional dyspepsia:

Adults: 15-30 mg once a day for 2 to 4 weeks.

Special populations

Elderly population

No dose adjustment is necessary. However, 30mg per day is the maximum daily dose.

Renal impairment:

No dose adjustment is necessary in renal failure – this also applies to patients on dialysis.

Paediatric population

Safety and efficacy in children has not been established.

Method of administration

Oral use

RAN-LANSOPRAZOLE should be preferably taken before a meal.

4.3 Contraindications

Hypersensitivity to lansoprazole or to any of the excipients of **RAN-LANSOPRAZOLE.**

Pregnancy and lactation (see section 4.6).

Severe liver impairment.

RAN-LANSOPRAZOLE is contraindicated with atazanavir and nelfinavir as it substantially reduces exposure to the HIV-protease inhibitor (see section 4.5).

4.4 Special warnings and precautions for use

Safety and efficacy in children has not been established.

Diagnosis of reflux oesophagitis:

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Exclusion of malignant ulcers:

Treatment with **RAN-LANSOPRAZOLE** may alleviate the symptoms of malignant ulcers and can delay diagnosis. Therefore, in the presence of symptoms such as, significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, or melaena, and when gastric ulcer is suspected or present, the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded prior to treatment with **RAN-LANSOPRAZOLE**.

Acute Interstitial Nephritis:

Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs) including LANCAP. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction and is associated with damage to the tubulointerstitium, leading to acute kidney injury. Patients may present with varying signs and symptoms from symptomatic hypersensitivity reactions to non-

specific symptoms of decreased renal function (e.g. malaise, nausea, anorexia). In reported case series, some patients were diagnosed on biopsy and in the absence of extra-renal manifestations (e.g., fever, rash or arthralgia). Interstitial nephritis may lead to renal failure. Discontinue **RAN-LANSOPRAZOLE** if acute interstitial nephritis develops (see section 4.8).

Proton pump inhibitors, such as lansoprazole as in **RAN-LANSOPRAZOLE**, are associated with an increased risk of subclinical acute or chronic interstitial nephritis associated with proton pump inhibitors (PPIs) leading to chronic renal inflammation and reduced renal function. Interstitial nephritis may progress to renal failure as it is not necessarily reversed when treatment is discontinued.

RAN-LANSOPRAZOLE should be used with caution in patients with liver impairment (see section 4.3).

In patients suffering from gastro-duodenal ulcers, the possibility of *H. pylori* infection as a aetiological factor should be considered. If **RAN-LANSOPRAZOLE** is used in combination with antibiotics for eradication therapy of *H.pylori,* then the instructions for the use of these antibiotics should also be followed.

Effect of prolonged use:

Daily treatment with acid-suppressing medicines such as **RAN-LANSOPRAZOLE** 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 acid-suppressing therapy have been reported. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.

Because of limited safety data for patients on maintenance treatment for longer than 1 year, regular review of the treatment and a thorough risk/benefit assessment should regularly be performed in these patients.

RAN-LANSOPRAZOLE is not indicated for mild gastrointestinal complaints such as nervous dyspepsia.

Occurrence of hypomagnesaemia:

Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like **RAN-LANSOPRAZOLE** 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 dysrhythmia can occur but they may begin insidiously and be overlooked. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia (see section 4.8).

In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of **RAN-LANSOPRAZOLE**.

For patients expected to be on prolonged treatment or who take **RAN-LANSOPRAZOLE** with digoxin or medicines that may cause hypomagnesaemia (e.g., diuretics), healthcare professionals should consider measuring magnesium levels before starting **RAN-LANSOPRAZOLE** treatment and periodically during treatment.

Bone fracture:

Proton pump inhibitors, such as **RAN-LANSOPRAZOLE**, especially if used in high doses and over long durations (>1 year), may increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. Patients should use the lowest dose and shortest duration of **RAN-LANSOPRAZOLE** therapy appropriate to the condition being treated.

Patients at risk of osteoporosis should receive care according to current clinical guidelines.

Concomitant use with methotrexate:

Concomitant use of **RAN-LANSOPRAZOLE** 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 **RAN-LANSOPRAZOLE** may be considered in some patients (see section 4.5).

Effects related to acid inhibition:

During long-term treatment, gastric glandular cysts have been reported in increased frequency. These physiological changes result from pronounced inhibition of gastric acid secretion.

Decreased gastric acidity increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with **RAN-LANSOPRAZOLE** may lead to an increased risk of gastro-intestinal infections such as *Salmonella* and *Campylobacter*.

Increased risk of Clostridium difficile associated diarrhoea:

Proton pump inhibitor (PPI) therapy like **RAN-LANSOPRAZOLE** may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD). This diagnosis should be considered for diarrhoea that does not improve. Patients should use the lowest dose and shortest duration of **RAN-LANSOPRAZOLE** therapy appropriate to the condition being treated.

Proton pump inhibitors, such as lansoprazole as in **RAN-LANSOPRAZOLE**, are associated with subacute cutaneous lupus erythematosus (SCLE). If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the medical practitioner should consider stopping **RAN-LANSOPRAZOLE**.

Effect on central nervous system:

RAN-LANSOPRAZOLE may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Possible porphyrinogenicity: Lansoprazole, as in **RAN-LANSOPRAZOLE**, is possibly porphyrinogenic and should be used only when no safer alternative is available, and precautions should be considered in all patients.

Patients should use the lowest dose and shortest duration of **RAN-LANSOPRAZOLE** therapy appropriate to the condition being treated.

Excipients

Sucrose

RAN-LANSOPRAZOLE contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take **RAN-LANSOPRAZOLE**.

4.5 Interactions with other medicines and other forms of interaction

There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death.

Patients treated with **RAN-LANSOPRAZOLE** and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Concomitant administration of PPIs such as **RAN-LANSOPRAZOLE** and methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly

leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of **RAN-LANSOPRAZOLE** may be considered in some patients.

Medicines with pH dependent absorption

RAN-LANSOPRAZOLE causes a profound and long-lasting inhibition of gastric acid secretion; therefore it is possible that **RAN-LANSOPRAZOLE** may interfere with the absorption of medicines where gastric pH is critical to bioavailability (e.g. itraconazole, ketoconazole, posaconazole,
ampicillin esters, iron salts, digoxin, atazanavir, dasatinib and erlotinib). If voriconazole is taken concomitantly with **RAN-LANSOPRAZOLE** the plasma concentration of both medicines may be increased.
Atazanavir: A study has shown that co-administration of lansoprazole (60 mg once daily) with atazanavir 400 mg to healthy volunteers resulted in a substantial reduction in atazanavir exposure (approximately 90 % decrease in AUC and C_{max}). **RAN-LANSOPRAZOLE** should not be co-administered with atazanavir and nelfinavir (see section 4.3).
Ketoconazole and itraconazole: The absorption of ketoconazole and itraconazole from the gastrointestinal tract is enhanced by the presence of gastric acid. Administration of **RAN-LANSOPRAZOLE** may result in sub-therapeutic concentrations of ketoconazole and itraconazole and the combination should be avoided.
Digoxin: Co-administration of **RAN-LANSOPRAZOLE** and digoxin may lead to increased digoxin plasma levels. The plasma levels of digoxin should therefore be monitored and the dose of digoxin adjusted if necessary when initiating and ending **RAN-LANSOPRAZOLE** treatment.

Medicines metabolised by P450 enzymes

Since **RAN-LANSOPRAZOLE** is a weak inducer of the cytochrome P450 system, the possibility exists for interactions with medicines which are metabolised via this system, such as warfarin, antipyrine, indomethacin, ibuprofen, or other nonsteroidal anti- inflammatory drugs (NSAIDS); oral contraceptives, phenytoin,
propranolol, prednisone, diazepam or clarithromycin.
Lansoprazole may increase plasma concentrations of medicines that are metabolised by CYP3A4. Caution is advised when combining **RAN-LANSOPRAZOLE** with medicines which are metabolised by this enzyme and have a narrow therapeutic window.

Theophylline: Lansoprazole reduces the plasma concentration of theophylline, which may decrease the expected clinical effect at the dose. Patients may require additional titration of the theophylline dosage when treatment with **RAN-LANSOPRAZOLE** is commenced or discontinued, to ensure clinically effective blood levels. Caution is advised when combining the two medicines.

Tacrolimus: Co-administration of lansoprazole increases the plasma concentrations of tacrolimus (a CYP3A and P-gp substrate) and result in a decreased clearance. Lansoprazole exposure increased the mean exposure of tacrolimus by up to 81 %. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with **RAN-LANSOPRAZOLE** is initiated or ended.

RAN-LANSOPRAZOLE has been shown to have no clinically significant interaction with amoxicillin.

Medicines which inhibit CYP2C19

- *Fluvoxamine:* A dose reduction may be considered when combining lansoprazole with the CYP2C19 inhibitor fluvoxamine. A study shows that the plasma concentrations of lansoprazole increase up to 4-fold.
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Medicines which induces CYP2C19 and CYP3A4

Enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin, and St John´s wort (*Hypericum perforatum*) can markedly reduce the plasma concentrations of lansoprazole.

Others

Sucralfate/Antacids: Sucralfate/Antacids may decrease the bioavailability of lansoprazole. Therefore **RAN-LANSOPRAZOLE** should be taken at least 1 hour after taking these medicines.

Clopidogrel: Concomitant administration of lansoprazole and clopidogrel in healthy subjects had no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of **RAN-LANSOPRAZOLE**.

The decrease in gastric activity with RAN-LANSOPRAZOLE may give false positive results in diagnostic investigations for neuroendocrine tumours and treatment should be stopped before such investigations.

Treatment with **RAN-LANSOPRAZOLE** may cause false-negative results in the urea breath test for Helicobacter pylori infection. It is recommended that a urea breath test should not be performed for at least 2 weeks after stopping treatment with **RAN-LANSOPRAZOLE**.

4.6 Fertility, pregnancy and lactation

Pregnancy

RAN-LANSOPRAZOLE is contraindicated in pregnancy.

Adequate and well-controlled studies in humans have not been done.

Breastfeeding

RAN-LANSOPRAZOLE is contraindicated in lactation.

It is not known whether lansoprazole is distributed into breast milk. However, lansoprazole or its metabolites are distributed into the milk of rats. Because lansoprazole has been shown to cause tumorigenic effects in animals, a decision should be made as to whether nursing should be discontinued or the medicine withdrawn, taking into account the importance of lansoprazole to the mother (see **section 4.3**).

4.7 Effect on ability to drive and operate machines

Adverse reactions such as dizziness, vertigo, visual disturbances and somnolence may occur (see section 4.8). Under these conditions the ability to react may be decreased. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machines or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable effects

Tabulated list of Adverse events:

MedDRA system organ class	**Frequency**	**Adverse reactions**
Infections and Infestations	*Unknown frequency*	*Clostridium difficile* associated diarrhoea.
Blood and lymphatic system disorders	*Less frequent*	Thrombocytopenia, anaemia, leucopenia, neutropenia, eosinophilia, agranulocytosis,

		pancytopenia, haemolysis, lymphadenopathy.
	Unknown frequency	Aplastic anaemia, haemolytic anaemia, thrombotic thrombocytopenic purpura.

Immune system disorders	*Less frequent*	Allergic reaction, bronchospasm, anaphylactic shock, angioedema, acute interstitial nephritis.
Endocrine disorders	*Less frequent*	Diabetes mellitus, goiter, hypothyroidism
Metabolism and nutrition disorders	*Less frequent*	Avitaminosis, gout, dehydration, hyperglycaemia/hypoglycaemia, peripheral oedema, weight gain/loss.
	Unknown frequency	Hypomagnesaemia (see section 4.4), hypocalcarmia[1], hypokalaemia[1].
Psychiatric disorders	*Less frequent*	Depression, insomnia, hallucination, confusion, abnormal dreams, agitation, aggression, amnesia, anxiety, apathy, dementia, depersonalisation, emotional lability, hostility aggravated, libido decreased/increased, nervousness, neurosis, sleep disorder
Nervous system disorders	*Frequent*	Headache, dizziness.
	Less frequent	Somnolence, tremor, convulsion, restlessness, vertigo, paraesthesia, increased sweating, hemiplegia, hyperkinesia, hypertonia, hypesthesia, parosmia, thinking abnormality; speech disorder
Eye disorders	*Less frequent*	Blurred vision, visual disturbances, abnormal

		vision, diplopia, amblyopia, blepharitis, cataract, conjunctivitis, dry eyes, eye disorder, eye pain, glaucoma, photophobia, retinal degeneration/disorder, visual field defect.
Ear and labyrinth disorders	*Less frequent*	Deafness, ear disorder, otitis media, tinnitus.
Cardiac disorders	*Less frequent*	Angina, dysrhythmia, bradycardia, myocardial infarction, palpitations, shock (circulatory failure), tachycardia, cardiospasm.
Vascular disorders	*Less frequent*	Migraine, cerebrovascular accident/cerebral infarction,-hypertension/hypotension, syncope, vasodilation.
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Asthma, bronchitis, increased cough, dyspnoea, epistaxis, haemoptysis, hiccup, laryngeal neoplasia, lung fibrosis, pharyngitis, pleural disorder, pneumonia, respiratory disorder, upper respiratory inflammation/infection, rhinitis, sinusitis, stridor
Gastrointestinal disorders	*Frequent*	Diarrhoea, nausea, vomiting, constipation and abdominal pain, flatulence, dry mouth or throat.
	Less frequent	Glossitis, taste abnormalities, taste loss, colitis, candidiasis of the oesophagus, pancreatitis, stomatitis, anorexia, abdomen enlarged, abnormal stools, bezoar, cholelithiasis, dyspepsia, dysphagia, enteritis, eructation, oesophageal stenosis,

		oesophageal ulcer, oesophagitis, faecal discolouration, gastric nodules/fundic gland polyps, gastritis, gastroenteritis, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal haemorrhage, gum haemorrhage, haematemesis, increased appetite, increased salivation, melaena, mouth ulceration, gastrointestinal moniliasis, rectal disorder, rectal haemorrhage, tenesmus, thirst, tongue disorder, ulcerative stomatitis.
Hepatobiliary disorders	*Frequent*	Increase in liver enzyme levels.
	Less frequent	Hepatitis, jaundice, hyperbilirubinaemia.
	Unknown frequency	Hepatotoxicity, hepatic failure or necrosis.
Skin and subcutaneous tissue disorders	*Frequent*	Skin rash, pruritus, urticaria.
	Less frequent	Alopecia, petechiae, purpura, erythema multiforme, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis, acne, contact dermatitis, dry skin, fixed eruption, hair disorder, maculopapular rash, nail disorder, skin carcinoma, skin disorder, peripheral oedema, subacute cutaneous lupus erythematosus.
Musculoskeletal, and connective tissue disorders	*Less frequent*	Arthralgia, myalgia, fracture of the hip, wrist or spine (see section 4.4), arthritis, bone disorder, joint disorder, leg cramps, musculoskeletal pain, myasthenia, ptosis,

		synovitis, back pain, neck pain, neck rigidity, pelvic pain.
Renal and urinary disorders	*Less frequent*	Dysuria, interstitial nephritis, kidney calculus, kidney pain, polyuria, urethral pain, urinary frequency, urinary tract infection, urinary urgency, urination impaired, urinary retention, in some patients renal failure has been reported concomitantly (see section 4.4).
Reproductive system and breast disorders	*Less frequent*	Gynaecomastia, galactorrhoea, abnormal menses, menorrhagia, menstrual disorder, breast enlargement, breast pain, breast tenderness, dysmenorrhoea, impotence, penis disorder, testis disorder, leucorrhoea, vaginitis.
General disorders and administration site conditions	*Frequent*	Fatigue.
	Less frequent	Asthenia, fever, oedema, hyperhidrosis, carcinoma, chills, flu syndrome, infection, malaise, pain, chest pain, halitosis.
Investigations	*Less frequent*	Increase in cholesterol and triglyceride levels, hyponatraemia.
	Unknown frequency	Increased creatinine, increased alkaline phosphatase, increased globulins, increased GGTP, increased/decreased/abnormal WBC, abnormal AG ratio, abnormal RBC, bilirubinaemia, increased blood potassium, increased blood urea, crystal urine present,

		decreased haemoglobin, increased/ decreased electrolytes, increased glucocorticoids, increased LDH, increased/ decreased/ abnormal platelets, increased gastrin levels and positive faecal occult blood. Urine abnormalities such as albuminuria, glycosuria, and haematuria were also reported.

[1] Hypocalcemia and/or hypokalaemia may be related to the occurrence of hypomagnesaemia in association with hypomagnesemia (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section 4.8.

The effects of overdose on lansoprazole in humans are not known.

In the case of suspected overdose the patient should be monitored. Lansoprazole is not significantly eliminated by haemodialysis. If necessary, gastric emptying, charcoal and symptomatic therapy is recommended.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 11.4.3 Medicines acting on the gastro-intestinal tract

Lansoprazole is an inhibitor of the gastric H^+ K^+-ATPase (proton pump). Lansoprazole inhibits gastric acid secretion in a dose related manner irrespective of the source of stimulation. Gastric secretory functions recover gradually following discontinuation of the medicine. Lansoprazole has no effect on histamine, gastrin or cholinergic receptors.

5.2 Pharmacokinetic properties

Absorption

Following oral administration, lansoprazole is well absorbed with a resultant bioavailability of approximately 78 %. The bioavailability is decreased if lansoprazole is taken with food. Peak serum concentrations are achieved approximately 1-2 hours following ingestion.

Distribution

Lansoprazole is highly protein bound (97 %).

Biotransformation

Lansoprazole is extensively metabolised via the hepatic cytochrome P450 system to the inactive, sulphated metabolites – sulphone, sulphide and 5-hydroxyllansoprazole. The half-life for lansoprazole is 1,4 to 1,5 hours.

Elimination

The main route of elimination is via the bile with 15-30 % of lansoprazole being excreted via the kidneys as the hydroxylated metabolite.

Special populations:

Elderly: The clearance of lansoprazole is decreased in the elderly, with elimination half-life increased approximately 50 to 100 %. Because the mean half-life in the elderly remains between 1,9 to 2,9 hours, repeated once daily dosing does not result in accumulation of lansoprazole. Peak plasma levels are not increased in the elderly, therefore no dose adjustment is necessary.

Renal impairment: In patients with severe renal insufficiency, plasma protein binding decreases by 1,0 to 1,5 % after administration of 60 mg of lansoprazole. Patients with renal insufficiency have a shortened elimination half-

life and decreased total AUC (free and bound). AUC for free lansoprazole in plasma, however, is not related to the degree of renal impairment, and C_{max} and T_{max} are not different from patients with healthy kidneys. No dosage adjustment is necessary in patients with renal impairment

Hepatic impairment: In patients with various degrees of chronic hepatic disease, the mean plasma half-life of lansoprazole is prolonged from 1,5 hours to 3,2 to 7,2 hours. An increase in mean AUC of up to 500 % has been observed at steady state in hepatically-impaired patients compared to healthy patients. Dose reduction in patients with severe hepatic disease should therefore be considered.

Race: The mean AUC of lansoprazole in Asian patients is approximately twice that observed in whites or African Americans, since the former population are more likely to have the CYP2C19 genotype that correlates with slow metabolism of proton pump inhibitors. This finding may contribute to heightened efficacy and/or toxicity in the Asian population.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:

Colloidal anhydrous silica

Hydroxypropyl methyl cellulose

Macrogol 300

Methacrylic acid ethylacrylate copolymer (1:1) dispersion 30 %,

Purified talc

Purified water

Sugar (sucrose) spheres

Titanium dioxide

Capsule shells:

15 mg: yellow cap/yellow body consisting of Gelatin, quinoline yellow, yellow iron oxide; titanium dioxide.

Printing Ink: Opacode Black S-I-8152 HV consisting of iron oxide black, shellac glaze, soya lecithin.

30 mg: purple cap/lavender body consisting of Azorubine; Indigo carmine; gelatin, titanium dioxide.

Printing Ink: ammonium hydroxide 2 %, ethanol, isopropyl alcohol, iron oxide black, N-butyl alcohol, propylene glycol, purified water, shellac glaze.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from moisture.

Do not remove the blister strips from the cartons until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

7 capsules are packed in cold form blister strips or aluminium strips.

Cold form blister strips comprise of a cold form laminate with a backing of aluminium foil sealed with a heat seal lacquer.

Aluminium strips comprise of aluminium foil laminated with low-density polyethylene.

Cartons contain 7, 14 or 28 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

A Sun Pharma Company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBER

RAN-LANSOPRAZOLE 15: A39/11.4.3/0251

RAN-LANSOPRAZOLE 30: A39/11.4.3/0252

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 April 2006

10. DATE OF REVISION OF THE TEXT

03 May 2024