PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

LANSOPRAZOLE UNICORN 15 (capsules)

LANSOPRAZOLE UNICORN 30 (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

LANSOPRAZOLE UNICORN 15: Each capsule contains 15 mg lansoprazole.

Contains sugar. Sugar spheres: 70,00 mg and Sucrose: 16,55 mg

LANSOPRAZOLE UNICORN 30: Each capsule contains 30 mg lansoprazole.

Contains sugar. Sugar spheres: 140,00 mg and Sucrose: 33,10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

LANSOPRAZOLE UNICORN 15: Capsules filled with white to light brown or slightly pink coloured pellets. The body of the hard gelatine capsule is white and the cap is red-brownish coloured.

LANSOPRAZOLE UNICORN 30: Capsules filled with white to light brown or slightly pink coloured pellets. The body and cap of the hard gelatine capsule are white.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

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

LANSOPRAZOLE UNICORN 30 is indicated for the short-term treatment of gastric ulcer.

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 two to four weeks.

Patients may respond to 15 mg once a day for two to four weeks, therefore individual dose adjustment should be considered.

LANSOPRAZOLE UNICORN 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. Depending on the endoscopic results, a repeat course of 4 weeks may be necessary.

Patients may respond to 15 mg once a day for four weeks which could have a repeat course of four weeks depends on endoscopic results.

Maintenance treatment for the prevention of gastro-oesophageal reflux:

15 mg once a day for a maximum period of one year, no clinical information is available for treatment longer than one year.

Functional dyspepsia:

15 – 30 mg once a day for 2 to 4 weeks.

Special populations:

Elderly: No dose adjustment is necessary. However, 30 mg 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:

The use of **LANSOPRAZOLE UNICORN** has not been studied in children. Treatment of small children below one year of age should be avoided as available data has not shown beneficial effects in the treatment of gastro-oesophageal reflux disease.

Method of administration:

LANSOPRAZOLE UNICORN should swallowed whole with a glass of water and not crushed or chewed.

LANSOPRAZOLE UNICORN should preferably be taken before a meal.

4.3 Contraindications

- Hypersensitivity to lansoprazole or to any of the ingredients.
- Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria. (see section 4.8)

- Pregnancy and lactation.
- Liver impairment.
- **LANSOPRAZOLE UNICORN** should not be used with atazanavir or nelfinavir, as it substantially reduces exposure to the HIV-protease inhibitor. (see section 4.5).

4.4 Special warnings and precautions for use

Children:

Safety and efficacy in children has not been established.

Malignant disease:

Treatment with **LANSOPRAZOLE UNICORN** 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 **LANSOPRAZOLE UNICORN**.

Acute interstitial nephritis

Acute interstitial nephritis has been observed in patients taking PPIs including **LASOPRAZOLE UNICORN**. Acute interstitial nephritis may occur at any point during therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue **LANSOPRAZOLE UNICORN** if acute interstitial nephritis develops. (see section 4.3)

Healthcare professionals should frequently monitor renal function, including urine analysis for haematuria and/or proteinuria in patients on treatment with PPIs. Patients should be advised to report any decrease in urine volumes or suspect that there is blood in their urine.

Malabsorption

Daily treatment with acid-suppressing medications such as **LANSOPRAZOLE UNICORN** 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 in the literature. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.

There have been reports of **LANSOPRAZOLE UNICORN** impairing the bioavailability of dietary vitamin C.

Fat malabsorption, secondary to increased deconjugation of bile acids caused by bacterial overgrowth in the jejunum, has also been reported with proton pump inhibitors such as **LANSOPRAZOLE UNICORN** therapy.

It has been suggested that proton pump inhibitors such as **LANSOPRAZOLE UNICORN** can also cause calcium malabsorption.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors, such as lansoprazole, is associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the healthcare professional should consider stopping treatment with **LANSOPRZOLE UNICORN**. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Alcohol and CNS depressants

The concomitant use of **LANSOPRAZOLE UNICORN** with alcohol or other central nervous system depressants may lead to drowsiness and impaired concentration.

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with **LANSOPRAZOLE UNICORN** for at least 3 months to one year. Serious manifestations of hypomagnesaemia such as fatigue,

tetany, delirium, convulsions, dizziness and ventricular dysrhythmia can occur, but may begin slowly and be overlooked. In most patients affects, symptoms improved after magnesium replacement and discontinuation of **LANSOPRAZOLE UNICORN**.

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

Bone fracture

LANSOPRAZOLE UNICORN, especially if administered in high doses, and for longer than one year, may increase the risk of hip, wrist and spine fracture, mainly in the elderly or in the presence of other recognised risk factors. Patients at risk of osteoporosis should receive appropriate care and should have an adequate intake of vitamin D and calcium. (See section 4.8.)

Clostridium difficile associated diarrhoea (CDAD)

LANSOPRAZOLE UNICORN may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD). A diagnosis of CDAD should be considered for patients taking **LANSOPRAZOLE UNICORN** who develop diarrhoea that does not improve. Patients should use the lowest dose and shortest duration of **LANSOPRAZOLE UNICORN** therapy appropriate to the condition being treated.

Reflux Oesophagitis gastric glandular cysts

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

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.

Gastrointestinal infections caused by bacteria

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

When prescribing **LANSOPRAZOLE UNICORN** for eradication of *Helicobacter pylori*, possible interactions for all components in the triple therapy should be considered. In patients suffering from gastro-duodenal ulcers, the possibility of *H. pylori* infection as an etiological factor should be considered. If 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.

There have been very rare reports of colitis in patients taking lansoprazole. Therefore, discontinuation of therapy should be considered in the case of severe and/or persistent diarrhoea.

Except for patients treated for the eradication of *H. pylori* infection, if diarrhoea persists, lansoprazole therapy should be discontinued. This is due to the possibility of microscopic colitis with thickening of the collagen bundle or infiltration of inflammatory cells noted in the large intestine submucosa. In majority of cases, symptoms associated with microscopiccolitis resolve on discontinuation of therapy with lansoprazole.

Long term use

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.

Laboratory tests

Serum gastrin levels increases in response to the decreased acid secretion, which occurs during treatment with antisecretory medicine. Increased chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, treatment with **LANSPRAZOLE UNICORN** 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 discontinuation of proton pump inhibitor (PPI) treatment.

Hepatic impairment:

Lansoprazole should be used with caution in patients with moderate and severe hepatic dysfunction (see sections 4.2 and 5.2).

Use with other medicines:

Co-administration of lansoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH, such as atazanavir and nelfinavir, due to significant reduction in their bioavailability (see section 4.5). If co-administration of lansoprazole with HIV protease inhibitors is unavoidable, close clinical monitoring is recommended.

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

Porphyria:

LANSOPRAZOLE UNICORN, is possibly porphyrinogenic and should be used only when no safer alternative is available and precautions should be considered in all patients.

Excipients:

LANSOPRAZOLE UNICORN contains sugar (sucrose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

Effects of LANSOPRAZOLE UNICORN on other medications

Medicines with pH dependent absorption

- **LANSOPRAZOLE UNICORN** causes a profound and long-lasting inhibition of gastric acid secretion, therefore it is possible that **LANSOPRAZOLE UNICORN** may interfere with the absorption of medicines where gastric pH is an important determinant of bioavailability (e.g. osaconazole, ampicillin esters, iron salts, digoxin, dasatinib and erlotinib).

HIV medications

- Co-administration of atazanavir with other proton-pump inhibitors such as **LANSOPRAZOLE UNICORN** has been shown to result in a substantial reduction in the bio-availability of atazanavir. Therefore **LANSOPRAZOLE UNICORN** must not be co-administered with atazanavir and nelfinavir (see ~~**CONTRAINDICATIONS**~~ section 4.3).

Ketoconazole and itraconazole

- The absorption of ketoconazole and itraconazole from the gastrointestinal tract is increased by the presence of gastric acid. Administration of **LANSOPRAZOLE UNICORN** may result in sub-therapeutic concentrations of ketoconazole and itraconazole. These combinations should be avoided.
- If voriconazole is taken concomitantly with **LANSOPRAZOLE UNICORN** the plasma concentration of both medicines may be increased.

Digoxin

- The absorption of unchanged digoxin may be enhanced if taken with **LANSOPRAZOLE UNICORN**, resulting in increased plasma concentrations. Plasma levels of digoxin should thus be monitored and if necessary the dose adjusted upon initiating and ending **LANSOPRAZOLE UNICORN** treatment.

Medicines metabolised by P450 enzymes

- The plasma concentraions of medicines that are metabolised by CYP3A4 may be increased by **LANSOPRAZOLE UNICORN**. Caution is advised when combining **LANSOPRAZOLE UNICORN** with medicines which are metabolised by this enzyme and have a narrow therapeutic window.

Theophylline:

- Concomitant administration of **LANSOPRAZOLE UNICORN** and theophylline shows a minor increase (10 %) in the clearance of theophylline. Due to the small magnitude and the direction of the effect on theophylline clearance, this interaction is unlikely to be of clinical concern. Nonetheless, patients may require additional titration of the theophylline dosage when treatment with **LANSOPRAZOLE UNICORN** is commenced or discontinued, to ensure clinically effective blood levels.

Tacrolimus:

- Co-administration of **LANSOPRAZOLE UNICORN** and increases the plasma concentrations of tacrolimus (a CYP3A and P-gp substrate). **LANSOPRAZOLE UNICORN** exposure increased the mean exposure of tacrolimus. Monitoring of tacrolimus plasma concentrations is advised when concomitant treatment with **LANSOPRAZOLE UNICORN** is initiated or ended.

Medicines transported by P-glycoprotein

- Lansoprazole has been observed to inhibit the transport protein, P-glycoprotein (P-gp) *in vitro*, however the clinical relevance of this is unknown.

Effects of other medicines on LANSOPRAZOLE UNICORN

Medicines which inhibit CYP2C19

Fluvoxamine:

- Fluvoxamine increases exposure to **LANSOPRAZOLE UNICORN** in patients who are extensive metabolisers, therefore dose reduction may need to be considered in patients taking these medicines concomitantly.

Medicines which induces CYP2C19 and CYP3A4

- Enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin, and St John's wort (*Hypericum perforatum*) can reduce the plasma concentrations of **LANSOPRAZOLE UNICORN.**

Others

Warfarin

- Reports of increased International Normalised Ratio (INR) and prothrombin time in patients receiving proton pump inhibitors, including **LANSOPRAZOLE UNICORN**, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Monitoring of patients receiving concomitant warfarin is recommended, since a minor reduction in the concentration of warfarin, increases in INR and prothrombin time may occur.

Clopidogrel:

- Concomitant administration of **LANSOPRAZOLE UNICORN** with clopidogrel in healthy

patients has 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 **LANSOPRAZOLE UNICORN**.

Sucralfate/Antacids:

- The concomitant administration of sucralfate/antacids may decrease the bioavailability and absorption of **LANSOPRAZOLE UNICORN**.
- **LANSOPRAZOLE UNICORN** should be taken at least 1 hour after taking these medicines.

Methotrexate:

- Concomitant administration of methotrexate (particularly in high doses) with **LANSOPRAZOLE UNICORN** may elevate and prolong serum concentrations of methotrexate and/or its metabolite hydromethotrexate. However, no formal drug interaction studies of high dose methotrexate with PPIs such as **LANSOPRAZOLE UNICORN** have been conducted (see section 4.4).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation have not been established. (See section 4.3)

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

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 medication withdrawn, taking into account the importance of lansoprazole to the mother.

4.7 Effects on the ability to drive and use machines

LANSOPRAZOLE UNICORN may lead to drowsiness and impaired concentration that may be

aggravated by the simultaneous intake of alcohol or other central nervous system depressants. (See section 4.8)

Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable effects

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders:	*Less frequent:*	Thrombocytopenia, anaemia, leukopenia, eosinophilia, haemolysis, lymphadenopathy, agranulocytosis, pancytopenia
Immune system disorders:	*Less frequent:*	Allergic reaction (including fever), angioedema, anaphylaxis
Metabolism and nutrition disorders:	*Less frequent:* *Frequency unknown:*	Gout, dehydration, hyperglycaemia / hypoglycaemia, peripheral oedema, weight gain/loss. Hypomagnesaemia, hypocalcaemia, hypokalaemia
Psychiatric disorders:	*Less frequent:* *Frequency unknown:*	Agitation, anxiety, apathy, confusion, depersonalisation, depression, emotional lability, hallucinations, hostility aggravated, nervousness, neurosis, thinking abnormality, insomnia, sleep disorder Visual hallucinations
Nervous system	*Frequent:*	Headache, dizziness

System Organ Class	Frequency	Side effects
disorders:	*Less frequent:*	Somnolence, insomnia, tremor, convulsion, hemiplegia, hyperkinesia, hypertonia, hypoesthesia, paraesthesia, vertigo, diplopia, parosmia, restlessness
	Frequency unknown:	Hemiplegia
Eye disorders:	*Less frequent:*	Blurred vision, abnormal vision, conjunctivitis, dry eyes, eye pain, photophobia, retinal degeneration/disorder, visual field defect, visual disturbances
	Frequency unknown:	Amblyopia, blepharitis, cataract, glaucoma
Ear and labyrinth disorders:	*Less frequent:*	Deafness, ear disorder, otitis media, tinnitus
Cardiac disorders:	*Less frequent:*	Chest pain, angina, dysrhythmia, bradycardia, myocardial infarction, palpitations, tachycardia, cardiospasm
Vascular disorders:	*Less frequent:*	Oedema, cerebrovascular accident/cerebral infarction, hypertension/hypotension, migraine, syncope, shock (circulatory failure), vasodilation
Respiratory, thoracic and mediastinal disorders:	*Less frequent:*	Asthma, bronchitis, cough increased, dyspnoea, epistaxis, haemoptysis, hiccough, pharyngitis, pleural disorder, pneumonia, respiratory disorder, upper respiratory inflammation/infection, rhinitis, sinusitis, stridor, parosmia

System Organ Class	Frequency	Side effects
Gastrointestinal disorders:	*Frequent:*	Diarrhoea, nausea, vomiting, constipation, flatulence, dry mouth or throat, abdominal pain, fundic gland polyps (benign)
	Less frequent:	Glossitis, taste abnormalities, ulcerative colitis, abdomen enlarged, halitosis, bezoar, colitis, dyspepsia, dysphagia, enteritis, eructation, oesophageal stenosis, oesophageal ulcer, oesophagitis, faecal discolouration, gastritis, gastroenteritis, gastrointestinal anomaly, gastrointestinal disorder, gastrointestinal haemorrhage, gum haemorrhage, haematemesis, increased appetite, increased salivation, melena, mouth ulceration, oral moniliasis, rectal disorder, rectal haemorrhage, stomatitis, tenesmus, thirst, tongue disorder, ulcerative stomatitis, taste loss, taste perversion, candidiasis of the oesophagus, pancreatitis
	Frequency unknown:	Collagenous colitis; Gastric glanducer cytes
Hepato-biliary disorders:	*Frequent:*	Elevation in hepatic enzymes
	Less frequent:	Cholelithiasis, hepatitis, jaundice mostly with liver injury (increase in up to twice the upper limit of normal range of hepatic enzymes), hyperbilirubinaemia

System Organ Class	Frequency	Side effects
Skin and subcutaneous tissue disorders:	*Frequent:* *Less frequent:* *Frequency unknown:*	Skin rash, pruritus, urticaria Alopecia, acne, contact dermatitis, dry skin, fixed eruption, hair disorder, maculopapular rash, nail disorder, skin disorder, sweating, petechiae, purpura, hair loss, erythema multiforme, photosensitivity, Steven-Johnson syndrome, toxic epidermal necrolysis Subacute cutaneous lupus erythematosus (see section 4.4)
Musculoskeletal, connective tissue and bone disorders:	*Less frequent:*	Arthralgia, myalgia, fracture of the hip, wrist or spine, arthritis, bone disorder, joint disorder, leg cramps, musculoskeletal pain, synovitis, back pain, chills, neck pain, neck rigidity, myasthenia
Renal and urinary disorders:	*Less frequent:*	Dysuria, kidney calculus, kidney pain, polyuria, urethral pain, urinary frequency, urinary tract infection, urinary urgency, urination impaired, interstitial nephritis
Reproductive system and breast disorders:	*Less frequent:*	Gynaecomastia, galactorrhoea, pelvic pain, libido decreased/increased abnormal menses, breast enlargement, breast pain, breast tenderness, dysmenorrhoea, leukorrhoea, menorrhagia, menstrual disorder, penis disorder, testis disorder, vaginitis
General disorders and administrative	*Frequent:* *Less frequent:*	Fatigue Fever, asthenia, anorexia, oedema, angioedema,

System Organ Class	Frequency	Side effects
site conditions:		fever, malaise, pain, hyperhidrosis, impotence
Investigations:	*Less frequent:*	Hyponatraemia, increase in cholesterol and triglyceride levels

Reporting of suspected adverse reactions

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

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of **LANSOPRAZOLE UNICORN**.

4.9 Overdose

The effects of an overdose of **LANSOPRAZOLE UNICORN** have not been studied, however acute toxicity is likely to be low.

Daily doses up to 180 mg have been administered without significant undesirable effects (See section 4.8).

There is no specific antidote for lansoprazole overdose, treatment is symptomatic and supportive.

LANSOPRAZOLE UNICORN is not removed from the circulation by hemodialysis. If necessary, gastric emptying, charcoal and symptomatic therapy are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Class: A. 11.4.3 Medicines acting on the gastro-intestinal tract.

Pharmacotherapeutic group: Proton pump inhibitors, **ATC code:** A02BC03

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 %).

Metabolism

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 hours and this does not alter during treatment.

Elimination

Lansoprazole is totally eliminated after oral administration. 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 subjects 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients: Disodium hydrogen phosphate dehydrate, gelatine capsules, maize starch, methacrylic acid – ethyl acrylate copolymer (1:1) 30% dispersion, polyethylene glycol 6000, polysorbate 80, povidone K-30, sodium lauryl sulphate, sucrose, sugar spheres, talc, and titanium dioxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25 ºC in a dry place.

Keep the capsules in the original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

LANSOPRAZOLE UNICORN 15 capsules are available in white HDPE bottles closed with a polypropylene tamper-evident cap with mounted desiccant insert containing 7, 14, 28 or 30 capsules.

LANSOPRAZOLE UNICORN 30 capsules are available in white HDPE bottles closed with a polypropylene tamper-evident cap with mounted desiccant insert containing 14, 28 or 30 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Unicorn Pharmaceuticals (Pty) Ltd

Corner Searle and Pontac Streets

Cape Town

8001

8. REGISTRATION NUMBER

LANSOPRAZOLE UNICORN 15: 40/11.4.3/0249

LANSOPRAZOLE UNICORN 30: 40/11.4.3/0250

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

June 2007

10. DATE OF REVISION OF THE TEXT

January 2021

DECLARATION

LANSOPRAZOLE UNICORN

Capsule

Each capsule contains 15 or 30 mg lansoprazole

1.3.1.1 Professional Information

The applicant confirms that the printed PI will comply with regulation 11 in terms of legibility of the printed PI.

The PI will be translated into one other official language.

I, **Cindi Benjamin** (Regulatory Pharmacist) hereby confirm that the PI has been checked for spelling and grammatical correctness.

