Professional Information for OSP: OPTIMAL SUPPORT PACKETS

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

OSP: OPTIMAL SUPPORT PACKETS
(PLUS™ TABLETS, AMBROTOSE AO® CAPSULES AND PHYTOMATRIX® TABLETS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PLUS™ tablets

Each tablet contains:

Dioscorea villosa L. (Wild Yam)	200 mg
[root, extract standardised to 12,5 % diosgenin (25 mg)]	
Glycine	200 mg
L-Glutamic acid	200 mg
L-Lysine (from L-Lysine HCl)	200 mg
L-Arginine (from L-Arginine HCl)	95 mg
Beta-sitosterol (from phytosterols)	25 mg
Boron glycine	10 mg
providing Boron	1 mg
Ambrotose® Complex	2,5 mg
providing Larix laricina (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	(1 mg)
Aloe vera (L.) Burm.f. (Aloe) [inner leaf juice powder]	(0,5 mg)
Anogeissus latifolia (Roxb. ex DC.) Wall. ex Guillem. & Perr. (Ghatti gum)	(0,5 mg)
Astragalus gummifer Labill. (Tragacanth)	(0,5 mg)

Sugar free.

Excipients with known effect:
Contains sugar alcohol (7,74 mg xylitol per tablet).

AMBROTOSE AO® CAPSULES

Each capsule contains:

Ambrotose Phyto Formula	333 mg
providing Arabic gum	(99,2 mg)

MANNATECH®

Xanthan gum	(99,2 mg)
Astragalus gummifer Labill. (Tragacanth)	(66,6 mg)
Anogeissus latifolia (Roxb. ex DC.) Wall. ex Guillem. & Perr. (Ghatti gum)	(63,1 mg)
Aloe vera (L.) Burm.f. (Aloe) [inner leaf juice powder]	(3,3 mg)
Phyt•Aloe® Complex	(2 mg)
providing *Allium cepa* L. (Onion) [bulb extract]	(0,18 mg)
Allium sativum L. (Garlic) [bulb extract]	(0,18 mg)
Brassica oleracea L. var. acephala DC. (Kale) [leaf extract]	(0,18 mg)
Brassica oleracea L. var. *botrytis* L. (Cauliflower) [flower/stalk extract]	(0,18 mg)
Brassica oleracea L. var. *capitata* L. (Cabbage) [leaf extract]	(0,18 mg)
Brassica oleracea L. var. gemmifera (DC.) Zenker (Brussels sprout) [aerial part extract]	(0,18 mg)
Brassica oleracea L. var. *italica* Plenck (Broccoli) [flower/stalk extract]	(0,18 mg)
Brassica rapa L. (Turnip) [root extract]	(0,18 mg)
Daucus carota L. (Carrot) [root extract]	(0,18 mg)
Lycopersicon esculentum Mill. (Tomato) [fruit extract]	(0,18 mg)
Ananas comosus (L.) Merr. (Pineapple) [fruit juice powder]	(0,08 mg)
Carica papaya L. (Papaya) [fruit extract]	(0,08 mg)
MTech AO blend®	117 mg
providing Quercetin dihydrate (from *Dimorphandra mollis* Benth.)	(86 mg)
Vitis vinifera L. (Grape) [skin, extract standardised to polyphenols 80 %]	(15 mg)
Camellia sinensis (L.) Kuntze (Green Tea) [leaf, 10:1 extract standardised to EGCG 50 % and caffeine 1 %]	(14 mg)
Terminalia ferdinandiana Exell (Australian Bush Plum) [fruit extract]	(3 mg)
Ascorbic acid (Vitamin C)	29 mg
Vitamin E (as mixed d-alpha-, d-beta-, d-delta- and d-gamma-tocopherols)	18 IU

Sugar free.

MANNATECH®

CONTAINS CAFFEINE (0,1 mg per capsule).
A cup of instant coffee contains approximately 80 mg of caffeine.

PHYTOMATRIX® tablets

Each tablet contains:

Dicalcium phosphate	340 mg
providing Calcium (elemental)	98,6 mg
Saccharomyces cerevisiae (baker's yeast)	307,18 mg
providing Niacin (Vitamin B_3)	3,67 mg
Zinc (elemental)	3,51 mg
Iron (elemental)	1,5 mg
Pantothenic acid (Vitamin B_5)	1,26 mg
Manganese (elemental)	0,6 mg
Pyridoxine (Vitamin B_6)	0,5 mg
Copper (elemental)	0,4 mg
Riboflavin (Vitamin B_2)	0,37 mg
Thiamine (Vitamin B_1)	0,34 mg
Folic acid	91,67 µg
Chromium (elemental)	50 µg
Selenium (elemental)	40 µg
Biotin (Vitamin B_7)	34,38 µg
Iodine	26,5 µg
Molybdenum (elemental)	20 µg
Vanadium (elemental)	20 µg
Malpighia glabra L. (Acerola)	115 mg
[fruit, extract standardised to 15 % (15 mg) ascorbic acid (Vitamin C)]	
Lithothamnion spp. (red algae)	100 mg
providing Calcium (elemental)	29 mg
Magnesium (elemental)	2,5 mg
Brassica oleracea L. (Broccoli)	30 mg
[floret, extract standardised to 4 % glucosinolates]	
Mixed tocopherols	23,57 mg
providing alpha-tocopherol (Vitamin E)	7,5 IU
Aloe vera (L.) Burm.f. (Aloe)	20 mg
[inner leaf juice powder]	
Rutin	20 mg
Vaccinium oxycoccos L. (Cranberry)	20 mg
[fruit, 12:1 extract providing 240 mg of dried herb equivalent]	
Vitis vinifera L. (Grape)	12,5 mg
[skin, extract standardised to 80 % polyphenols]	
Beta-carotene (from Blakeslea trispora)	3,6 mg
providing retinol (Vitamin A)	165 IU
Boron glycinate	2 mg
providing Boron (elemental)	0,2 mg
Glycine	0,6 mg
Ergocalciferol (Vitamin D_2)	100 IU
Cyanocobalamin (Vitamin B_{12})	1,5 µg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

PLUS™
Tablets.
Off-white to yellow, elongated film-coated tablet.

AMBROTOSE AO® CAPSULES
Capsules.
Clear hard vegetable capsules containing a yellow-green powder.

PHYTOMATRIX®
Tablets.
Yellow-brown, oval shaped tablet with a clear coating.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OSP is a combination of three complementary medicine products intended to supplement the diet with vitamins, minerals, trace minerals, antioxidants and herbal extracts to assist and support the immune system, endocrine system and general well-being.

4.2 Posology and method of administration

Adults:
Take the contents of one packet (one capsule and four tablets) with 250 mL water or juice twice daily with a meal.

Do not exceed the recommended dosage.

Children:
Not suitable for children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.
- Abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, haemorrhoids or diarrhoea.
- Pregnancy or lactation (see section 4.6).

4.4 Special warnings and precautions for use

Surgery:
OSP may increase the risk of bleeding or interfere with blood glucose and blood pressure control if used perioperatively. Patients should be advised to discontinue OSP at least 2 weeks prior to any surgical procedures.

Thyroid disorders:
OSP should be used with caution in patients with hypothyroidism.

Gastrointestinal conditions:

Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use.
If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking OSP, patients should stop taking OSP or reduce the dose.

Kidney disorders:
Patients with a kidney disorder or a history of kidney stones should consult a health care provider prior to use.

Cardiovascular disorders:
Patients with cardiovascular disease, hypotension, or a history of a myocardial infarction (MI) should consult a health care provider prior to use.

Iron deficiency:
Patients should consult a health care provider prior to use if they have an iron deficiency.

Diabetes mellitus:
OSP may affect blood glucose levels and dose adjustment of antidiabetic medicine might be necessary. Patients with diabetes should consult a health care provider prior to use.

Liver disorders:
Patients should consult a health care provider prior to use if they have a liver disorder. Patients should be advised to stop taking OSP and consult a relevant health care provider if they develop symptoms of liver trouble such as yellowing of the skin or eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.

Low protein diet:
Patients following a low protein diet should consult a health care provider prior to use.

Long-term use:
Patients should consult a relevant health care provider for use beyond 12 weeks.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:
OSP may potentiate the effects of anticoagulant or antiplatelet medicines or herbal supplements with blood thinning effects. Concomitant use may increase the risk of bruising and bleeding.

Antidiabetic medicines:
Concomitant use of OSP with antidiabetic medicines or herbal supplements with hypoglycaemic potential may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antibiotic medicines:
OSP may reduce the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking OSP.

Cardiac medicines:
Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines) should consult a health care provider prior to use. The use of OSP with antihypertensive medicine or herbal supplements with hypotensive effects may have additive blood pressure-lowering effects when used concomitantly. Caution is advised.

Medicines causing electrolyte imbalances:
Patients taking thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult a health care provider prior to use.

Protease inhibitors:
Patients taking protease inhibitors should consult a health care provider prior to use.

Levothyroxine:
OSP may reduce levothyroxine absorption. Advise patients to take levothyroxine and OSP at least 4 hours apart.

4.6 Fertility, pregnancy and lactation

OSP should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

OSP may cause side effects such as sleepiness or dizziness and can affect the ability to drive a vehicle and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of OSP are known.

4.8 Undesirable effects

OSP is generally well tolerated.

Immune system disorders:
Frequency unknown: hypersensitivity and/or allergic reactions.

Metabolism and nutrition disorders:
Frequency unknown: reduced appetite.

Psychiatric disorders:
Frequency unknown: insomnia.

Nervous system disorders:
Frequency unknown: headache, sleepiness, fatigue, dizziness, drowsiness.

Vascular disorders:
Frequency unknown: flushing.

Gastrointestinal disorders:
Frequency unknown: abdominal pain and cramps, stomach upset, bloating, belching, flatulence, dyspepsia, nausea, vomiting, diarrhoea, constipation.

Hepato-biliary disorders:
Frequency unknown: hepatotoxicity.

Skin and subcutaneous tissue disorders:
Frequency unknown: skin rash or itching.

General disorders and administration site conditions:
Frequency unknown: fever.

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

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product.

Arabic gum is an indigestible, water-soluble dietary fibre. It is not absorbed from the gastrointestinal tract and is fermented to short-chain fatty acids by bacteria in the large intestine.

Xanthan gum is a polysaccharide produced by fermenting glucose, sucrose or lactose with the bacterium *Xanthomonas campetris*.

When ingested, the bulk of tragacanth stretches the intestinal wall, increasing peristalsis. It increases stool weight and decreases gastrointestinal (GI) transit time.

Aloe vera (L.) Burm.f. (Aloe) has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

Allium cepa L. (Onion) contains plant sterols and flavonoids such as quercetin. Quercetin in onion is metabolised in the liver and excreted in the urine.

Allium sativum L. (Garlic) has antioxidant and immunologic effects. Garlic contains allicin and other constituents, such as S-allyl cysteine, which is well absorbed, metabolised in the liver and kidneys and excreted primarily in the urine and faeces.

Brassica oleracea L. var. acephala DC. (Kale) contains carotenoids (including lutein and beta-carotene), glucosinolates, ascorbigen, calcium, magnesium, phosphorus, potassium, vitamin K (phylloquinone), vitamin C, vitamin A, iron

and folate, which can assist with the maintenance of good health.

Brassica oleracea L. var. botrytis L. (Cauliflower) contains constituents, such as carotenoids, vitamin C, vitamin A and vitamin E, which have antioxidant effects.

Brassica oleracea L. var. capitata L. (Cabbage) has antioxidant effects. Isothiocyanates from cabbage are conjugated with glutathione, metabolised to N-acetylcysteine and excreted in the urine.

Brassica oleracea L. var. gemmifera (DC.) Zenker (Brussels sprout) contains constituents, such as carotenoids, fiber, vitamin C, vitamin A, vitamin E and isothiocyanates, which have antioxidant and immune-boosting effects.

Brassica oleracea L. var. italica Plenck (Broccoli) contains glucosinolates which are metabolised into indoles and isothiocyanates and are excreted in the urine.

Brassica rapa L. (Turnip) contains fiber, carotenoids, vitamin C and vitamin A, which have antioxidant effects.

Daucus carota L. (Carrot) has antioxidant effects. Carrot contains beta-carotene, which is absorbed and metabolised to vitamin A.

Lycopersicon esculentum Mill. (Tomato) has immunomodulating effects. It contains the carotenoid, lycopene, which is better absorbed from tomato products than from fresh tomatoes.

Ananas comosus (L.) Merr. (Pineapple) contains the proteolytic enzyme, bromelain, which is distributed in plasma and blood and has an elimination half-life of 6 – 9 hours.

Carica papaya L. (Papaya) contains papain as well as carotenoids and has antioxidant and immunostimulant effects.

Quercetin dihydrate is a dietary flavonoid and has antioxidant effects. It is not well absorbed in the gastrointestinal tract, protein-bound in plasma, methylated in the liver and excreted in the urine.

Vitis vinifera L. (Grape) extract contains polyphenols which have antioxidant effects. Polyphenols are metabolised to phenolic acids and are excreted in the urine.

Camellia sinensis (L.) Kuntze (Green Tea) extract is a source of antioxidants for the maintenance of good health and has immunologic effects. Green Tea extract has been shown to rapidly increase general levels of plasma polyphenols as well as epigallocatechin gallate (EGCG), which is increased in the fasting state. EGCG has an elimination half-life of approximately 5 hours and is excreted in the urine.

Terminalia ferdinandiana Exell (Australian Bush Plum) has antioxidant properties.

Ascorbic acid (Vitamin C) is a water-soluble vitamin with antioxidant properties. It helps to maintain proper immune function and to metabolise fats and proteins. It is readily absorbed from the gastrointestinal tract and is primarily excreted in the urine.

Vitamin E is an antioxidant for the maintenance of good health. It is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Dioscorea villosa L. (Wild Yam) contains diosgenin which have hormonal effects. Diosgenin is metabolised in the liver and eliminated via the bile.

Glycine is an amino acid with antioxidant properties and is involved in muscle protein synthesis. It is rapidly absorbed in the blood and is eliminated within hours after ingestion.

L-Glutamic acid is a source of an amino acid involved in

muscle protein synthesis and can have immune boosting effects. It is absorbed in the jejunum, primarily oxidised and a small portion is used for gluconeogenesis.

L-Lysine is a source of an essential amino acid involved in muscle protein synthesis and for the maintenance of good health. L-Lysine may also help in collagen formation. It is catabolised in the liver, leading to acetyl-CoA and is excreted in the faeces and the urine.

L-Arginine is an amino acid involved in muscle protein synthesis. It has antioxidant, hormonal and immunological effects. It has an oral bioavailability of 68 %, is broken down into nitric oxide and L-citrulline and has an elimination half-life of approximately 80 minutes.

Beta-sitosterol is a plant sterol that helps support the functioning of the immune system. It also has hormonal and lipid-lowering properties. Beta-sitosterol is absorbed after oral intake and is excreted in bile and faeces.

Boron is a trace mineral that is a factor in the maintenance of good health. It is well-absorbed from the gastrointestinal tract and is excreted unchanged in the urine, with a half-life of 21 hours.

Larch Arabinogalactan has immune-boosting properties. It is resistant to digestion in the stomach and small intestine and is instead fermented by human colonic microflora to produce acetate, butyrate and propionate.

Calcium contributes to the development and maintenance of bones and teeth and is a factor in the maintenance of good health. Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Niacin (Vitamin B_3) is a water-soluble vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is rapidly absorbed from the gastrointestinal tract and is excreted mainly via urine.

Zinc helps to maintain immune function and helps the body to metabolise carbohydrates, fats and proteins. It is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.

Iron helps to form red blood cells and helps in their proper function. Its absorption is variable and is enhanced by the presence of ascorbic acid. Most of the iron absorbed is incorporated into haemoglobin and is mostly excreted in the faeces.

Pantothenic acid (Vitamin B_5) is an essential B vitamin that helps to metabolise carbohydrates, fats and proteins and is a factor in the maintenance of good health. It is the precursor of coenzyme A (CoA) and is excreted in the urine.

Manganese is an essential nutrient that is involved with normal cell growth and generation of the immune response. It is not well absorbed and is cleared hepatically.

Pyridoxine (Vitamin B_6) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. It is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Copper helps to produce and repair connective tissue and to form red blood cells. It is absorbed primarily from the small intestines, mainly distributed to the skeleton and muscles and excreted in the urine.

Riboflavin (Vitamin B_2) helps to metabolise carbohydrates, fats and proteins and contributes to tissue formation. Oral supplementation results in the production of 7-hydroxymethylriboflavin in blood plasma and is excreted in the urine.

Thiamine (Vitamin B_1) is a water-soluble B-vitamin that helps to metabolise carbohydrates, fats and proteins and contributes to normal growth. It is absorbed at the proximal part of the small intestines. It occurs in the body as the metabolically active form, thiamine diphosphate, and is excreted in the urine.

Folic acid is a water-soluble vitamin that helps the body to metabolise proteins and form red blood cells. After absorption, it is reduced to tetrahydrofolate and then converted to L-methylfolate. It is excreted mainly in the urine.

Chromium is a mineral that has antioxidant properties and helps to support healthy glucose metabolsim. The small percentage of chromium that is absorbed, approximately 0,5 % to 2 %, is rapidly excreted in the urine and unabsorbed chromium in the faeces.

Selenium is a mineral with antioxidant properties for the maintenance of good health. The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase. It is excreted mainly in the urine.

Biotin is an essential, water-soluble B vitamin that helps to metabolise carbohydrates, fats and proteins. It is completely absorbed after oral administration. Biotin metabolites are formed by beta-oxidation, sulfur oxidation, or both, and is excreted in the urine.

Iodine contributes to the normal production of the thyroid hormones and normal thyroid function. It is absorbed through the stomach and duodenum and is converted to iodide. Iodine is excreted mainly in the urine, with small amounts excreted in faeces, sweat and saliva.

Molybdenum is an essential trace mineral that helps the body to metabolise proteins. It is readily absorbed from the gastrointestinal tract and is mainly excreted in the urine.

Vanadium is a trace mineral that is factor in the maintenance of good health. Only about 5 % is absorbed with highest concentrations found in the liver, kidneys and bone. Vanadium is excreted primarily in the urine.

Malpighia glabra L. (Acerola) fruit is a rich source of vitamin C. There is some evidence that vitamin C is more bioavailable when ingested in acerola than when taken as an ascorbic acid dietary supplement. Vitamin C is excreted in the urine.

Magnesium, a mineral that contributes to the maintenance of good health, has antioxidant and immune-boosting properties. It is absorbed throughout the gastrointestinal tract, distributed in the skeleton and soft tissue, and excreted primarily via the kidneys.

Brassica oleracea L. (Broccoli) is metabolised into isothiocyanates such as sulforaphane which may have anti-inflammatory and antioxidant properties. Sulforaphane conjugates with glutathione after absorption, is metabolised to N-acetylcysteine and is excreted in the urine.

Rutin is a flavonoid with antioxidant effects. It is hydrolysed in the gastrointestinal tract to release quercetin.

Vaccinium oxycoccos L. (Cranberry) and its constituents, particularly proanthocyanidins and quercetin, have antioxidant activity. After ingestion, Cranberry compounds are absorbed and excreted in the urine.

Vitamin A is a fat-soluble vitamin that contributes to immune function. It is readily absorbed from the gastrointestinal tract and is excreted primarily in the urine.

Boron is a trace mineral that is a factor in the maintenance of good health. It is well-absorbed from the gastrointestinal tract and is excreted unchanged in the urine, with a half-life of 21 hours.

Ergocalciferol (Vitamin D_2) is a fat-soluble vitamin that helps in the development and maintenance of bones and teeth and helps with the absorption and use of calcium and phosphorous. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Cyanocobalamin (Vitamin B_{12}) is an essential water-soluble vitamin that contributes to normal red blood cell formation. It is absorbed in the terminal ileum and has a half-life of about 25 – 30 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

PLUS™
Croscarmellose sodium (E468)
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Silicon dioxide (E551)
Spectrablend™ CC [containing hydroxypropyl methylcellulose (E464), calcium carbonate (E170), medium chain triglyceride (MCT) and xylitol (E967)]
Stearic acid (E570).

AMBROTOSE AO® CAPSULES
Citric acid powder (E330)
Vegetable capsule [containing hydroxypropyl methylcellulose (E464)].

PHYTOMATRIX®
Croscarmellose sodium (E468)
Magnesium stearate (E572)
Microcrystalline cellulose (E460)
Opadry® NS coating [containing vegetable hydroxypropyl methylcellulose (E464) and vegetable glycerin (E422)]
Silicon dioxide (E551).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.

6.5 Nature and contents of container

One (1) AMBROTOSE AO® CAPSULE, two (2) PHYTOMATRIX® tablets and two (2) PLUS™ tablets are packed inside a clear/foil packet. 60 packets are packed inside a recyclable gusseted bag.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville, 7551
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

January 2022.