Professional Information for AMBROTOSE® COMPLEX CAPSULES

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

AMBROTOSE® COMPLEX CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Ambrotose® Complex	400 mg
Oryza sativa L. (Rice starch) [seed powder]	(250 mg)
Larix laricina (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	(90 mg)
Astragalus gummifer Labill. (Tragacanth)	(30 mg)
Manapol® *Aloe vera* (L.) Burm.f. (Aloe) [inner leaf gel, 415:1 extract, providing 12,5 g fresh herb equivalent]	(30 mg)
β-carotene (from *Blakeslea trispora* fungus)	200 µg
providing Vitamin A	55 IU

Sugar free.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.
Beige with orange specks free flowing powder in a clear capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMBROTOSE® COMPLEX CAPSULES is a combination complementary medicine intended to assist and provide support for the immune system.

4.2 Posology and method of administration

Adults: Take 1 capsule with a glass of water or juice, twice daily.

Do not exceed the recommended dosage.

4.3 Contraindications

- Hypersensitivity to β-carotene, Ambrotose® Complex (see section 2) or to any of the excipients listed in section 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.

4.4 Special warnings and precautions for use

AMBROTOSE® COMPLEX CAPSULES might interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue AMBROTOSE® COMPLEX CAPSULES at least 2 weeks prior to any surgical procedures.

Patients with a cardiac or kidney disorder should consult a health care provider prior to use.

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking AMBROTOSE COMPLEX POWDER, patients should stop taking AMBROTOSE® COMPLEX CAPSULES or reduce the dose.

If a patient is a tobacco smoker, is taking statins to lower cholesterol levels, or has cardiovascular disease, a health care provider should be contacted prior to use.

4.5 Interaction with other medicines and other forms of interaction

Cardiac or diuretic medicines:
Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines), thiazide diuretics, corticosteroids, liquorice root, or other medicines or health products that may aggravate electrolyte imbalance, should consult with a health care provider prior to use.

Anticoagulant or antiplatelet medicines:
AMBROTOSE® COMPLEX CAPSULES may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects.

4.6 Fertility, pregnancy and lactation

AMBROTOSE® COMPLEX CAPSULES should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

AMBROTOSE® COMPLEX CAPSULES is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:
Less frequent: hypersensitivity reactions.

Gastrointestinal disorders:
Less frequent: abdominal pain and cramps, bloating, flatulence.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of AMBROTOSE® COMPLEX CAPSULES is important. It allows continued monitoring of the benefit/risk balance of AMBROTOSE® COMPLEX POWDER. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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.

Mechanism of action:
Aloe has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

Larch arabinogalactan has immune-boosting properties.

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

Vitamin A is a fat-soluble vitamin that plays a role in the maintenance of good health.

β-carotene is a Pro-vitamin A carotenoid with antioxidant properties.

Rice starch has antioxidant properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule (containing carrageenan, hydroxypropyl methylcellulose (E464) and potassium acetate),
dl-alpha-tocopherol,
modified food starch,
silicon dioxide powder (E551),
stearic acid powder (E570).

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.
Keep the bottle tightly closed.
Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

HDPE container with a PP cap containing 60 capsules.

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

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

May 2024.