Professional Information for ADVANCED AMBROTOSE® 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
ADVANCED AMBROTOSE® CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

β-carotene (from *Blakeslea trispora* fungus)	0,59 mg
providing Vitamin A	(32,3 IU)
Ambrotose® Complex	334 mg
providing *Larix laricina* (Du Roi) K. Koch or *Larix occidentalis* Nutt. (Larch Arabinogalactan)	(194,3 mg)
Aloeprime® *Aloe vera* (L.) Burm.f. (Aloe), [freeze-dried extract powder]	(37 mg)
Manapol® *Aloe vera* (L.) Burm.f. (Aloe) [inner leaf gel, 415:1 extract, providing 2,1 g fresh herb equivalent]	(5,0 mg)
Astragalus gummifer Labill. (Tragacanth)	(34 mg)
Oryza sativa L. (Rice starch) [seed powder]	(36 mg)
Glucosamine hydrochloride	(26 mg)
Undaria pinnatifida (Wakame) [fronds, 5:1 extract, providing 8,4 mg dried herb equivalent]	(1,7 mg)

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 clear capsule.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
ADVANCED AMBROTOSE® CAPSULES is a combination complementary medicine intended to provide support for the immune system and help maintain healthy digestive function.

4.2 Posology and method of administration

Adults: Take two (2) capsule with a glass of water or juice.

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

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

Patients with faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever should consult a health care provider prior to use.

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

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

4.5 Interaction with other medicines and other forms of interaction

Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medications), 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.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

ADVANCED AMBROTOSE® 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 ADVANCED AMBROTOSE® CAPSULES is important. It allows continued monitoring of the benefit/risk balance of ADVANCED AMBROTOSE® CAPSULES. 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.

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.

Glucosamine hydrochloride has immune-boosting properties.

Wakame is a source of fucoidans which aid in stimulating the immune system.

Vitamin A is a fat-soluble vitamin that contributes to immune function.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule (containing carrageenan [E407], hydroxypropyl methylcellulose [E464] and potassium acetate [E261])
Stearic acid.

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 120 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
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

November 2022.

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