



Professional Information for AMBROTOSE AO®

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

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1. NAME OF THE MEDICINE

AMBROTOSE AO® CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Ambrotose Phyto Formula	333 mg
providing Arabic gum	(99,2 mg)
Xanthan gum	(99,2 mg)
<i>Astragalus gummifer</i> Labill. (Tragacanth)	(66,6 mg)
<i>Anogeissus latifolia</i> (Roxb. ex DC.) Wall. ex Guillem. & Perr. (Ghatti gum)	(63,1 mg)
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	(3,3 mg)
[inner leaf juice powder]	
Phyt•Aloe® Complex	(2 mg)
providing <i>Allium cepa</i> L. (Onion)	(0,18 mg)
[bulb extract]	
<i>Allium sativum</i> L. (Garlic)	(0,18 mg)
[bulb extract]	
<i>Brassica oleracea</i> L. var. <i>acephala</i> DC. (Kale)	(0,18 mg)
[leaf extract]	
<i>Brassica oleracea</i> L. var. <i>botrytis</i> L. (Cauliflower)	(0,18 mg)
[flower/stalk extract]	
<i>Brassica oleracea</i> L. var. <i>capitata</i> L. (Cabbage)	(0,18 mg)
[leaf extract]	
<i>Brassica oleracea</i> L. var. <i>gemmifera</i> (DC.) Zenker (Brussels sprout)	(0,18 mg)
[aerial part extract]	
<i>Brassica oleracea</i> L. var. <i>italica</i> Plenck (Broccoli)	(0,18 mg)
[flower/stalk extract]	
<i>Brassica rapa</i> L. (Turnip)	(0,18 mg)
[root extract]	
<i>Daucus carota</i> L. (Carrot)	(0,18 mg)

[root extract]	
<i>Lycopersicon esculentum</i> Mill. (Tomato)	(0,18 mg)
[fruit extract]	
<i>Ananas comosus</i> (L.) Merr. (Pineapple)	(0,08 mg)
[fruit juice powder]	
<i>Carica papaya</i> L. (Papaya)	(0,08 mg)
[fruit extract]	
MTech AO blend®	117 mg
providing Quercetin dihydrate (from <i>Dimorphandra mollis</i> Benth.)	(86 mg)
<i>Vitis vinifera</i> L. (Grape)	(15 mg)
[skin, extract standardised to polyphenols 80 %]	
<i>Camellia sinensis</i> (L.) Kuntze (Green Tea)	(14 mg)
[leaf, 10:1 extract standardised to EGCG 50 % and caffeine 1 %]	
<i>Terminalia ferdinandiana</i> Exell (Australian Bush Plum)	(3 mg)
[fruit extract]	
Ascorbic acid (Vitamin C)	29 mg
Vitamin E (as mixed d-alpha-, d-beta-, d-delta- and d-gamma-tocopherols)	

Sugar free.

CONTAINS CAFFEINE (0,1 mg per capsule).

A cup of instant coffee contains approximately 80 mg of caffeine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Clear hard vegetable capsules containing a yellow-green powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AMBROTOSE AO® CAPSULES is a complementary medicine intended to provide multiple sources of antioxidants for the maintenance of good health and assist the immune system and general well-being.

4.2 Posology and method of administration

Adults:

Take one capsule twice daily, with a glass of water or juice.

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:

AMBROTOSE AO® CAPSULES may increase the risk of bleeding or interfere with blood glucose control if used perioperatively. Patients should be advised to discontinue AMBROTOSE AO® CAPSULES at least 2 weeks prior to any surgical procedures.

Thyroid disorders:

AMBROTOSE AO® CAPSULES 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 AMBROTOSE AO® CAPSULES, patients should stop taking AMBROTOSE AO® CAPSULES or reduce the dose.

Kidney disorders:

Patients with a kidney disorder 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:

AMBROTOSE AO® CAPSULES 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 AMBROTOSE AO® CAPSULES 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.

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

AMBROTOSE AO® CAPSULES 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.

Amoxicillin:

AMBROTOSE AO® CAPSULES may reduce the absorption of amoxicillin. Doses should be separated by at least 2 hours.

Cardiac medicines:

Patients taking cardiac medicines (e.g. cardiac glycosides or antidysrhythmic medicines) should consult a health care provider prior to use.

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.

4.6 Fertility, pregnancy and lactation

AMBROTOSE AO® CAPSULES contains Aloe vera which is contraindicated during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

AMBROTOSE AO® CAPSULES is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Gastrointestinal disorders:

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

Hepato-biliary disorders:

Frequency unknown: hepatotoxicity.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of AMBROTOSE AO® CAPSULES is important. It allows continued monitoring of the benefit/risk balance of AMBROTOSE AO® 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.

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 campestris*.

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 (phyloquinone), 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid powder (E330)

Vegetable capsule [containing hydroxypropyl methylcellulose (E464)].

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 silver PP flip-cap containing 60 capsules and a cotton wad.

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

October 2021.