



Professional Information for MANNACLEANSE™

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

MANNACLEANSE™ CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Ambrotose™ Complex	1 mg
<i>Larix laricina</i> (Du Roi) K. Koch or	
<i>Larix occidentalis</i> Nutt. (Larch Arabinogalactan)	(0,4 mg)
<i>Aloe vera</i> (L.) Burm.f. (Aloe)	(0,2 mg)
[dry inner leaf juice]	
<i>Astragalus gummifer</i> Labill. (Tragacanth)	(0,2 mg)
[stem]	
<i>Anogeissus latifolia</i> (Roxb. ex DC.) Wall. ex	
Guillem. & Perr. (Ghatti gum)	(0,2 mg)
[exudate]	
Fibre blend	375 mg
<i>Avena sativa</i> L. (Oat fibre)	(249 mg)
<i>Plantago indica</i> L. (Black psyllium husk)	(100 mg)
[seed]	
<i>Ribes nigrum</i> L. (Black currant)	(12,5 mg)
[fruit]	
<i>Amorphophallus konjac</i> K.Koch (Glucomannan)	(12,5 mg)
[konjac root]	
<i>Chondrus crispus</i> (Carrageenan)	(1 mg)
Botanical blend	72, 5 mg
<i>Foeniculum vulgare</i> Mill. (Fennel)	(12,5 mg)
[seed]	
<i>Trigonella foenum-graecum</i> L. (Fenugreek)	(12,5 mg)
[seed]	
<i>Zingiber officinale</i> Roscoe (Ginger)	(12,5 mg)
[root powder]	
Citrus bioflavonoids (flavonoids mixture)	(12,5 mg)
[fruit rind]	

<i>Rosmarinus officinalis</i> L (Rosemary) [leaf]	(12,5 mg)
<i>Mentha × piperita</i> L. (Peppermint) [leaf]	(10 mg)
Fatty acid blend	60 mg
<i>Linum usitatissimum</i> L. (Flaxseed)	(25 mg)
<i>Helianthus annuus</i> L. (Sunflower lecithin)	(10 mg)
<i>Oryza sativa</i> L (Rice bran)	(10 mg)
Sodium caprylate	(10 mg)
<i>Borago officinalis</i> L. (Borage oil) [seed]	(5 mg)
Gut flora promoting blend	40 mg
<i>Cichorium intybus</i> L. (Inulin) [dried chicory root juice]	(35 mg)
Beta-glucans	(5 mg)
Probiotic flora blend (50 million CFU)	12 mg
<i>Bacillus coagulans</i> (1,0 x 10 ⁹ CFU/g)	(1,8 mg)
<i>Lactobacillus acidophilus</i> (0,4 x 10 ¹⁰ CFU/g)	(4,1 mg)
<i>Lactobacillus plantarum</i> (0,4 x 10 ¹⁰ CFU/g)	(4,1 mg)
<i>Bifidobacterium bifidum</i> (0,1 x 10 ¹⁰ CFU/g)	(1 mg)
<i>Lactobacillus casei</i> (0,1 x 10 ¹⁰ CFU/g)	(1 mg)
Enzyme blend	10 mg
Alpha amylase [from <i>Aspergillus oryzae</i>]	(6 mg)
Lactase [from <i>Aspergillus oryzae</i>]	(2,9 mg)
Cellulase [from <i>Trichoderma longibrachiatum</i>]	(0,63 mg)
Neutral protease [from <i>Bacillus licheniformis</i>]	(0,4 mg)
Lipase [from <i>Rhizopus oryzae</i>]	(0,07 mg)

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsules.

Beige to light brown powder in a clear capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MANNACLEANSE™ is a combination complementary medicine containing a proprietary blend of fibres, botanicals, enzymes, probiotics and sources of fatty acids designed to promote proper colon function and to support intestinal health.

4.2 Posology and method of administration

Adults: Take 2 capsules twice daily, with a glass of water or juice. Taking MANNACLEANSE™ without enough liquid may cause choking (see section 4.4). Take MANNACLEANSE™ capsules between meals to achieve maximum benefit and effectiveness. Do not exceed the recommended dosage.

4.3 Contraindications

- Hypersensitivity to the active ingredients (see section 2) or to any of the excipients listed in section 6.1.
- Patients with immune-compromised conditions (e.g. acquired immunodeficiency syndrome (AIDS), lymphoma, patients undergoing long-term corticosteroid treatment).
- 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

Choking: Taking MANNACLEANSE™ without adequate fluid may cause it to swell and block the throat or oesophagus and may cause choking. Patients should not take MANNACLEANSE™ if they have difficulty swallowing.

Patients experiencing chest pain, vomiting, difficulty in swallowing or breathing after taking MANNACLEANSE™, should seek immediate medical attention.

Surgery:

MANNACLEANSE™ might interfere with blood glucose control and increase the risk of bleeding during and after surgical procedures. Patients should be advised to discontinue MANNACLEANSE™ at least 2 weeks prior to any surgical procedures (see section 4.5).

Hypotension:

MANNACLEANSE™ might have hypotensive effects and may exacerbate hypotension and lead to syncope in patients with existing low blood pressure (see section 4.5).

Gastro-intestinal conditions:

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

If abdominal pain, cramps, spasms and/or diarrhoea is experienced after taking MANNACLEANSE™, patients should stop taking MANNACLEANSE™ or reduce the dose.

Patients should consult a health care provider if they have gastrointestinal lesions/ulcers or want to use MANNACLEANSE™ for a prolonged period.

Patients should stop use and consult a health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persist beyond 3 days.

Kidney and blood disorders:

Patients with gallstones, anaemia or a kidney disorder should consult a health care provider prior to use.

Cross-sensitivity:

Patients allergic to ragweed, chrysanthemums, marigolds or daisies (the Asteraceae/ Compositae family) might have an allergic reaction to MANNACLEANSE™.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

MANNACLEANSE™ may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antibiotic medicines:

Concomitant use of certain antibiotic medicines with MANNACLEANSE™ may decrease its effectiveness. The administration of antibiotic medicines and MANNACLEANSE™ should be separated by at least 2 hours.

Antidiabetic medicines:

Concomitant use of MANNACLEANSE™ with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antihypertensive medicines:

MANNACLEANSE™ may have hypotensive effects. Concomitant use with antihypertensive medicines may have additive effects on lowering blood pressure and increase the risk of hypotension.

Medicines causing electrolyte imbalances:

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.

Anti-inflammatory medicines:

Patients taking prescription medicines or anti-inflammatory medicines should consult a relevant health care provider prior to use, as MANNACLEANSE™ may alter the effectiveness of these medicines.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

MANNACLEANSE™ is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Less frequent: hypersensitivity/allergic reactions

Gastrointestinal disorders:

Frequent: abdominal/gastrointestinal discomfort, heartburn
diarrhoea, burping

Less frequent: bloating, flatulence, abdominal distension
gastrointestinal cramps.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of MANNACLEANSE™ is important. It allows continued monitoring of the benefit/risk balance of MANNACLEANSE™. 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.

Ginger helps to relieve digestive upset including lack of appetite, nausea, digestive spasms, indigestion, dyspepsia, and flatulent colic (carminative).

Peppermint aids in digestion and helps to relieve an upset stomach.

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

Alpha-amylase and cellulase are digestive enzymes commonly used together with other digestive enzymes for digestive disorders.

Lactase is a digestive enzyme that helps with the digestion of foods containing lactose.

Lipase is a digestive enzyme that aids in fat digestion.

Protease is a digestive enzyme that helps with the digestion of proteins.

Fennel increases gastric acid secretion and the activity of digestive enzymes.

Inulin and beta-glucans provides a source of fibre for the maintenance of good health and helps to support and maintain a healthy digestive system.

Bifidobacteria and lactobacillus are considered beneficial bacteria and taken for the purpose of re-colonising areas where they normally would occur.

Bacillus coagulan is used therapeutically as a probiotic.

Borage oil provides a source of essential fatty acids/omega-6 fatty acids/linoleic acid (LA) for the maintenance of good health.

Rice bran contains beta-sitosterol and other phytosterols, as well as alpha-linolenic acid, which might increase the concentration of fatty acids such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Sunflower oil is high in linoleic acid and provides a source of polyunsaturated fat in the diet.

Flaxseed is used in herbal medicine as a bulk-forming laxative to promote bowel movements and to provide gentle relief of constipation and/or irregularity. It also provides a source of essential acids for the maintenance of good health.

Fenugreek is used in herbal medicine as a digestive tonic to aid digestion, to help relieve dyspepsia and gastritis, and as a mild laxative.

Citrus bioflavonoids provides a source of antioxidants.

Rosemary is used in herbal medicine to help relieve indigestion.

Glucomannan promotes bowel movements by increasing bulk volume and water content.

Black currant has antioxidant properties.

Black psyllium swells in water, forming a gelatinous mass which keeps the feces soft and increases bulk, promoting peristalsis and producing a laxative effect.

Oats can increase stool weight and accelerate colonic transit time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule (containing hypromellose),
CompactCell® (containing microcrystalline cellulose
rice extract and sunflower oil),
dicalcium diphosphate dihydrate,
peppermint flavour,
silicon dioxide (E551).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 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

White PE container with a white polypropylene 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

February 2022.