



Professional Information for MANNA-C™

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

MANNA-C™ CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

| | |
|---|------------|
| Ascorbic acid (Vitamin C) | 26,5 mg |
| [from <i>Malpighia glabra</i> L. (Acerola) fruit extract] | |
| Ambrotose® Complex | 42,5 mg |
| <i>Larix laricina</i> (Du Roi) K. Koch or | |
| <i>Larix occidentalis</i> Nutt. (Larch Arabinogalactan) | (25 mg) |
| <i>Aloe vera</i> (L.) Burm.f. (Aloe) | (9,5 mg) |
| [dry inner leaf juice] | |
| <i>Astragalus gummifer</i> Labill. (Tragacanth) | (8 mg) |
| [stem] | |
| Herbal blend | 199 mg |
| <i>Salvia officinalis</i> L. (Sage) | (60 mg) |
| [leaf powder] | |
| <i>Aloysia citriodora</i> Palau (Lemon verbena) | (45 mg) |
| [leaf powder] | |
| <i>Achillea millefolium</i> L. (Yarrow) | (23,25 mg) |
| [flower powder] | |
| <i>Terminalia ferdinandiana</i> Exell (Wild bush plum) | (23 mg) |
| [dried puree powder] | |
| <i>Mentha × piperita</i> L. (Peppermint) | (15,95 mg) |
| [leaf powder] | |
| <i>Nepeta cataria</i> L. (Catnip) | (15 mg) |
| [leaf powder] | |
| <i>Eupatorium perfoliatum</i> L. (Boneset) | (9 mg) |
| [aerial parts powder] | |
| <i>Marrubium vulgare</i> L. (White horehound) | (7,8 mg) |
| [aerial parts powder] | |

Excipients with known effect:

Contains sugar: Each capsule contains 48,8 mg maltodextrin.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Hard capsules.

Brownish-green powder in a clear capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MANNA-C™ is a combination complementary medicine intended to supplement your diet with Vitamin C sourced from acerola fruit and to assist in the promotion of general well-being.

4.2 Posology and method of administration

Adults: Take 2 capsules daily as needed, with a glass of water or other liquid. MANNA-C™ can be taken with or without food.

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.
- 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.
- Seizure disorders such as epilepsy.
- Pregnancy or lactation.

4.4 Special warnings and precautions for use

Bleeding disorder:

MANNA-C™ decreases platelet aggregation and may increase the risk of bleeding (see section 4.5).

Surgery:

MANNA-C™ can reduce blood glucose levels and might interfere with blood glucose control during and after surgical procedures. Patients should be advised to discontinue MANNA-C™ at least 2 weeks prior to any surgical procedures (see section 4.5).

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 MANNA-C™, patients should stop taking MANNA-C™ or reduce the dose.

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 MANNA-C™.

4.5 Interaction with other medicines and other forms of interaction**Antidiabetic medicines:**

Concomitant use of MANNA-C™ 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:

MANNA-C™ 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.

4.6 Fertility, pregnancy and lactation

MANNA-C™ should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects**Immune system disorders:**

Less frequent: hypersensitivity reactions.

Metabolism and nutrition disorders:

Less frequent: loss of appetite.

Nervous system disorders:

Frequent: headache, sleepiness.

Less frequent: dizziness.

Gastrointestinal disorders:

Frequent: nausea, vomiting, heartburn, abdominal cramps,
gastrointestinal obstruction, diarrhoea.

Less frequent: abdominal pain, bloating, flatulence, dry mouth,
excessive salivation.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of MANNA-C™ is important. It allows continued monitoring of the benefit/risk balance of MANNA-C™. 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 and boneset has immune-boosting properties.

Lemon verbena and white horehound has antioxidant and anti-inflammatory properties.

Peppermint and catnip 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 weight and decreases gastrointestinal (GI) transit time.

Vitamin C is an antioxidant and plays a role in the maintenance of good health.

Sage has antioxidant properties and is traditionally used in herbal medicine to help provide relief of upset stomach and flatulence.

Wild bush plum contains phytochemicals with antioxidant properties.

Arrow flower is traditionally used for stomach ulcers and other gastrointestinal problems.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule (containing hypromellose)
Sodium starch glycosylate
Stearic acid (E570).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 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 polypropylene cap containing 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Mannatech South Africa (Pty) Ltd
Viscount Office Park, 11 Viscount Road
Bedfordview, Gauteng 2007
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.