

The Real Thing Medicinal Mushrooms Capsules

Complementary Medicine. Western Herbal Medicine.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

THE REAL THING MEDICINAL MUSHROOMS CAPSULES contains *Agaricus blazei* (himematsutake) 66,7 mg, *Cordyceps sinensis* (caterpillar) 66,7 mg, *Ganoderma lucidum* (reishi) 66,7 mg, *Grifola frondosa* (maitake) 66,7 mg, *Lentinula edodes* (shiitake) 66,7 mg, and *Trametes versicolor* (turkey tail) 66,7 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING MEDICINAL MUSHROOMS CAPSULES contains:

	<u>Per capsule</u>	<u>Per 2 capsules</u>
<i>Agaricus blazei</i> (himematsutake) [Full spectrum]	66,7 mg	133,4 mg
<i>Cordyceps sinensis</i> (cordyceps, caterpillar) [Full spectrum]	66,7 mg	133,4 mg
<i>Ganoderma lucidum</i> (reishi) [Full spectrum]	66,7 mg	133,4 mg
<i>Grifola frondosa</i> (maitake) [Full spectrum]	66,7 mg	133,4 mg
<i>Lentinula edodes</i> (shiitake) [Full spectrum]	66,7 mg	133,4 mg
<i>Trametes versicolor</i> (turkey tail) [Full spectrum]	66,7 mg	133,4 mg

The inactive ingredients include magnesium stearate (vegetable origin) and vegetable (hypromellose) capsule shell. The capsules are sugar-free. For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING MEDICINAL MUSHROOMS CAPSULES is a clear, hard vegetable capsule shell, size 1, containing a light brown to brown powder with fine dark specks.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING MEDICINAL MUSHROOMS CAPSULES is a western herbal medicine with a specially formulated powdered blend of 6 organic mushrooms combined to:

- enhance the immune system;
- provide anti-oxidant activity that helps to maintain the body's good health;
- help increase energy and resistance to stress in cases of mental and physical fatigue related to stress.

4.2 Posology and method of administration

Adults 18 years and older: Take 2 (two) capsules orally daily with a glass of water or as prescribed by the patient's healthcare practitioner.

Best taken after a meal to avoid digestive upset.

Paediatric population

THE REAL THING MEDICINAL MUSHROOMS CAPSULES is not suitable for use in children. The safety and efficacy in children under 18 years of age has not been established.

4.3 Contraindications

- Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Advise patient to consult a healthcare practitioner if symptoms persist or worsen.

If patient has diabetes, advise patient to not to take more than the prescribed dose and to consult a health care practitioner prior to use.

Avoid use of *agaricus blazei* in patients with liver disease.

Lentinula edodes might stimulate the immune function and might exacerbate autoimmune diseases.

Cordyceps sinensis might alter the management of autoimmune diseases by either stimulating or suppressing the immune function, therefore use with caution or avoid using.

Ganoderma lucidum may have antiplatelet activity and in high doses might increase risk of bleeding in people with certain bleeding disorders.

There may be possible excessive bleeding during and after surgical procedures.

There is possible increased hypoglycaemic effect which might interfere with blood glucose control during and after surgical procedures.

Advise patients to discontinue THE REAL THING MEDICINAL MUSHROOMS CAPSULES at least 2 weeks prior to elective surgery.

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING MEDICINAL MUSHROOMS CAPSULES affecting other medicines:

Cordyceps sinensis and *Grifola frondosa* may increase risk of bleeding when used with anticoagulants. High doses of *Ganoderma lucidum* in combination with anticoagulant products might increase the risk of bleeding. Advise patient to consult a healthcare professional prior to use if taking anti-coagulants.

There is possible increased hypoglycaemic effect if it is used with other products that also lower blood glucose levels.

Ganoderma lucidum and *Grifola frondosa* taken concurrently with antihypertensive products might increase the risk of hypotension.

Lentinula edodes might decrease the effects of immunosuppressive therapy. ¹⁰⁽ⁱ⁾

4.6 Fertility, pregnancy and lactation

Advise patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. Insufficient information is available. Alternatively patients should not take this product.

No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING MEDICINAL MUSHROOMS CAPSULES may have a minor influence on the ability to drive and use of machines due to possible undesirable effects.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently documented side effects are gastro-intestinal disturbances.

b. List of adverse reactions

Side effects for the combination have not been documented. The following effects have been documented for the active ingredients:

Blood and lymphatic disorders

Ganoderma lucidum can cause nose bleed and bloody stools.

Lentinula edodes can cause eosinophilia.

Nervous system disorders

Ganoderma lucidum can cause dizziness (frequent), insomnia (less frequent) and headache (less frequent).

Lentinula edodes can cause prickling in the hands of patients experiencing dermatitis, and malaise.

Eye disorders

Lentinula edodes can cause conjunctivitis (less frequent) in patients with dermatitis.

Respiratory, thoracic and mediastinal disorders

Ganoderma lucidum can cause respiratory allergy to its spores, sore throat and runny nose.

Gastrointestinal disorders

Agaricus blazei has caused gastro-intestinal symptoms such as nausea (frequent), diarrhoea (frequent) and abdominal discomfort (frequent).

Cordyceps sinensis might cause mild gastro-intestinal disturbances such as diarrhoea (less frequent), constipation (less frequent) and abdominal discomfort (less frequent).

Ganoderma lucidum can cause dryness of mouth (frequent), throat or nasal cavity, nausea (frequent), stomach upset (frequent) and diarrhoea (less frequent).

Grifola frondosa has caused gastrointestinal effects such as nausea (less frequent), diarrhoea (frequent) and epigastric pain (frequent).

Lentinula edodes can cause abdominal discomfort such as nausea (frequent), pain, vomiting (frequent) and diarrhoea (frequent). Problems with swallowing or mouth ulcers have been associated with *Lentinula edodes* dermatitis.

Hepato-biliary disorders

Agaricus blazei might cause hepatotoxicity in compromised patients (less frequent).

Skin and subcutaneous tissue disorders

Ganoderma lucidum can cause itching (frequent), rash (frequent) and other skin reactions.

Lentinula edodes can cause dermatitis (less frequent) and a photosensitivity reaction which includes rash and pruritus after exposure to the sun (less frequent).

Frequencies of all adverse effects are not known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare practitioners are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**” found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail adr@therealthing.co.za

4.9 Overdose

With an overdose, side effects can be precipitated and/or be of increased severity.

Insufficient reliable information is available. In the event of overdosage, advise the patient to stop taking the supplement. Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING MEDICINAL MUSHROOMS CAPSULES belongs to Category D Complementary Medicines, class 33.6 Western Herbal Medicine.

It is a specially formulated powdered blend of 6 organic mushrooms, which individually have all been used in western herbal medicine and are known to have anti-oxidant activity. The synergistic activities of the different components in mushrooms provide immunomodulating activity and support the immune system.

The anti-oxidant and immunomodulating activities are particularly due to polysaccharides, in particular beta-glucans.

The combination assists with -

- supporting and enhancing the immune system;
- immunomodulating effects;
- antioxidant activity that provides cytoprotective activity thereby maintaining healthy cellular functions;
- helping to increase energy and resistance to stress (mental and physical fatigue related to stress).

5.2 Pharmacokinetic properties

For all mushrooms there is insufficient reliable information available about their pharmacokinetics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients include:

- magnesium stearate (vegetable origin)
- vegetable (hypromellose) capsule shell.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING MEDICINAL MUSHROOMS CAPSULES has a shelf life of 3 years when stored in a cool, dry place at or below 25 ° C.

6.4 Special precautions for storage

Store out of direct sunlight. Keep container tightly closed.

6.5 Nature and contents of container

THE REAL THING MEDICINAL MUSHROOMS CAPSULES are packed in a 75 ml amber glass bottle with a child resistant 38 mm polypropylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 60 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

Alternatively, it may be packed with a non-child resistant cap fitted with a plastic tamper-evident shrink sleeve.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD

9 Westlake Drive,

Westlake 7945, Cape Town

Telephone: 021-701 0244

E-mail: info@therealthing.co.za

8. REGISTRATION NUMBER

(To be allocated)

9. DATE OF FIRST AUTHORISATION

(To be allocated)

10. DATE OF REVISION OF THE TEXT

This is the first edition.

PI011/0, 31/10/2022