

The Real Thing MSM-Body Capsules

The Real Thing MSM-Body Powder

Complementary Medicine. Health Supplement.

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 MSM-BODY CAPSULES contains 900 mg MSM (methylsulfonylmethane) per capsule.

THE REAL THING MSM-BODY POWDER contains 2 000 mg MSM (methylsulfonylmethane) per half teaspoon, i.e. 2,5 ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING MSM-BODY CAPSULES contains:

	Per capsule	Per 3 capsules
MSM (methylsulfonylmethane)	900 mg	2 700 mg
*Providing sulphur (elemental)	300 mg	900 mg

*Elemental quantities calculated.

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

THE REAL THING MSM-BODY POWDER contains:

	Per single dose (2,5 ml / 2 g)	Per daily dose (5 ml / 4 g)
MSM (methylsulfonylmethane)	2 000 mg	4 000 mg
*Providing sulphur (elemental)	682 mg	1 364 mg

*Elemental quantities calculated.

There are no inactive ingredients. The powder is sugar free.

3 PHARMACEUTICAL FORM

THE REAL THING MSM-BODY CAPSULES is a clear, hard vegetable capsule shell, size 00, containing white to off-white powder.

THE REAL THING MSM-BODY POWDER is a white to off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING MSM-BODY CAPSULES and THE REAL THING MSM-BODY POWDER are health supplements that:

- Provide support for healthy joints, joint mobility and joint comfort.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

CAPSULES: Adults 18 years and older: Take 3 (three) capsules orally in divided doses per day with a glass of water. Do not take more than 2 capsules per single dose. Do not take more than 6 capsules per day.

POWDER: Adults 18 years and older: Take half a teaspoon (2 000 mg) orally once to three times per day with a glass of water. Do not take more than 2 000 mg per single dose. Do not take more than 6 000 mg per day.

Take with food. Take for a minimum of 4 weeks to see beneficial effects. Advise patient to consult a healthcare practitioner for prolonged use. Do not take at bedtime.

Paediatric population

THE REAL THING MSM-BODY CAPSULES and THE REAL THING MSM-BODY POWDER are not suitable for use in children unless under the care of a relevant healthcare practitioner.

4.3 Contraindications

Do not use this product if:

- Hypersensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Advise patient to consult a healthcare practitioner if symptoms worsen.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Insufficient reliable information is available. Advise patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING MSM-BODY CAPSULES and THE REAL THING MSM-BODY POWDER may have a minor influence on the ability to drive and use machines, due to possible undesirable effects such as fatigue and difficulty concentrating.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently occurring adverse reactions are gastrointestinal.

b. List of adverse reactions:

Immune system disorders

Increase allergy symptoms.

Nervous system disorders

Headache, fatigue, insomnia and difficulty concentrating.

Gastrointestinal disorders

Nausea (frequent), diarrhoea (frequent), mild bloating (frequent) and gastrointestinal discomfort (frequent), constipation, indigestion.

Skin and subcutaneous disorders

Pruritus (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 providers 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 MSM-BODY CAPSULES and THE REAL THING MSM-BODY POWDER belong to category D Complementary Medicines, Health Supplements, class 34.13 Other.

Methylsulfonylmethane (MSM) is a sulphur compound that supports healthy joints, joint mobility and joint comfort. MSM serves as a source of sulphur for the amino acids, cysteine and methionine. These sulphur-containing amino acids are involved in muscle protein synthesis and the maintenance of joint health.

5.2 Pharmacokinetic properties

Supplemental MSM crosses the blood-brain barrier. It serves as a source of sulphur in the body. It is excreted in the urine.

Paediatric population

No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients for the capsules include:

- magnesium stearate (vegetable origin)
- vegetable (Hypromellose) capsule shell

There are no inactive ingredients in the powder.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING MSM-BODY CAPSULES and THE REAL THING MSM-BODY POWDER have a shelf life of 2 years when stored in a cool, dry place at or below 25 °C.

6.4 Special precautions for storage

Store in an airtight container.

6.5 Nature and contents of container

THE REAL THING MSM-BODY CAPSULES is packed in a 200 ml amber glass bottle with a non-child resistant 45 mm polyethylene 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 90 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

THE REAL THING MSM-BODY POWDER is packed in a sealed plastic bag inside a cardboard container with an inner aluminium liner, a metal base and top, and a tamper proof seal with a clear plastic lid. The pack contains 240 g powder. Alternatively, THE REAL THING MSM-BODY POWDER is packed in a 300 ml amber glass bottle with a 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. The cap is fitted with a plastic tamper-evident shrink sleeve. The bottle contains 240 g powder.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD
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8 REGISTRATION NUMBER

(To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated)

10 DATE OF REVISION OF THE TEXT

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