

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

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

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

MEGASLIM Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Two capsules contain:

L-Carnitine tartrate	600 mg
Magnesium oxide	345,4 mg
providing Magnesium (elemental)	200 mg

Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Size 0, purple capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

MEGASLIM Fat Burner helps to support muscle tissue repair in individuals involved in resistance training, helps to improve physical performance when used in conjunction with a training regimen

and delay fatigue during physical activity. MEGASLIM Fat Burner helps to support fat metabolism and fat oxidation.

4.2 Posology and method of administration

Take 2 – 3 capsules daily with water for best results. MEGASLIM should be taken during a moderate exercise program. Take 2 – 4 hours prior to exercise.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to the active substances (L-Carnitine and magnesium) or to any of the excipients listed in section 6.1.
- L-Carnitine is contraindicated in patients with renal disease (on dialysis), liver disease, history of seizures.
- Pregnancy and lactation (see section 4.6)
- Not suitable for children under the age of 18 years.

4.4 Special warnings and precautions for use

- If you are receiving insulin or antidiabetic medication. Monitor for hypoglycaemia (see section 4.5).

Consult your relevant health care provider prior to use if you:

- are pregnant or breastfeeding; or
- have a liver disease, a kidney disease, or a seizure disorder

4.5 Interaction with other medicines and other forms of interaction

MEGASLIM may:

- Increase the effect of antidiabetic medication, and
- Decrease the effectiveness of thyroid medication
- Decrease the absorption of tetracycline and bisphosphonates.

Doses should be separated by at least 2 hours before, or 4 hours after taking MEGASLIM capsules.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

No information available.

Pregnancy

The safety of MEGASLIM in pregnancy has not been established. Avoid use.

Breastfeeding

The safety of MEGASLIM in lactation has not been established. Avoid use.

Fertility

No fertility data available.

4.7 Effects on ability to drive and use machines

No data is available, but no effect is expected on your ability to drive and use machines.

4.8 Undesirable effects

Frequency unknown:

Nausea, vomiting, diarrhoea, abdominal pain, heartburn, gastritis, bloating, body odour and seizures.

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

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

4.9 Overdose

An overdose may intensify the listed side effects and include nausea and vomiting. Discontinue use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category D Complementary Medicine: Health supplement 34.12 Multiple substance formulation.
L-Carnitine is a non-essential amino acid that helps support muscle tissue repair in individuals involved in resistance training and helps improve physical performance when used in conjunction with a training regimen. L-Carnitine supports fat metabolism and fat oxidation.

Magnesium is a mineral that contributes to the maintenance of normal muscle function and is a factor in the maintenance of good health.

5.2 Pharmacokinetic properties

No data is available for the proposed formulation.

5.3 Preclinical safety data

Not known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Magnesium stearate

Mocha Flavour

Polyvinylpyrrolidone K30

Talc powder

Capsule shell:

Size 0 purple body capsule

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Light/moisture sensitive.

Store in the original package/container.

6.5 Nature and contents of container

60 capsules in a container with a white lid.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Crux Pharmaceuticals

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Marketed by:

Cedarpharm (Pty) Ltd

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8 REGISTRATION NUMBER(S)

To be allocated

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF TEXT

October 2023