

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

DIS-CHEM GOLD L-CARNITINE vegecapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

L-Carnitine 200 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegecapsules.

Size 0, clear vegecapsules containing a white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD L-CARNITINE is an antioxidant and workout support supplement.

4.2 Posology and method of administration

Adults 18 years and older: One (1) to two (2) vegecapsules daily, two to four hours prior to exercise.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients should consult a healthcare practitioner prior to using DIS-CHEM GOLD L-CARNITINE:

- If the patient suffers from kidney disease, liver disease, or a seizure disorder.

4.5 Interaction with other medicines and other forms of interaction

- Patients must consult a healthcare practitioner if they are taking any other medicine (including complementary or traditional medicines).
- Patients should consult a healthcare practitioner prior to use if they are using any of the following medication: anticoagulants; thyroid hormone replacement drugs.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that DIS-CHEM GOLD L-CARNITINE does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: abdominal cramps, abdominal pain, anorexia, diarrhoea, gastritis, heartburn, nausea, vomiting.

Other disorders

Frequent: fish-like body odour.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.1 Amino Acids.

Complementary Medicine: Health Supplement.

5.1 Pharmacodynamic properties

L-carnitine is an antioxidant and workout support supplement.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD L-CARNITINE.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dicalcium phosphate
Magnesium stearate
Silicon dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Glass amber bottle with a gold child-resistant screw cap.
Pack size: 60 vegecapsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for the Dis-Chem Group
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@dischem.co.za
0860 347 243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.