

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 VITAMIN C & ZINC vegecapsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

Ascorbic Acid (Vitamin C)	100 mg
Zinc (as Zinc Oxide)	15 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegecapsules.

Size 0, clear vegecapsules containing a white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD VITAMIN C & ZINC contributes to the maintenance and function of the immune system.

4.2 Posology and method of administration

Adults and children 9 years and older: One (1) vegecapsule daily.

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 who suffer from chronic kidney disease; hyperoxaluria; kidney stones or who have a history of oxalate kidney stones.
- Patients who have diabetes mellitus should use caution due to possible interference caused by vitamin C with glucose determinations.
- Patients with glucose-6-phosphate dehydrogenase deficiency.

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: warfarin; desferrioxamine; estrogens; fluphenazine; protease inhibitors; antibiotics; penicillamine.

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 VITAMIN C & ZINC does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: gastrointestinal disturbances including abdominal pain, diarrhoea, nausea and vomiting.

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 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

5.1 Pharmacodynamic properties

Vitamin C and **zinc** contribute to the maintenance and function of the immune system.

5.2 Pharmacokinetic properties

Ascorbic acid (vitamin C) is readily absorbed from the gastrointestinal tract and is widely distributed in the body

tissues. Concentrations are higher in leucocytes and platelets than in erythrocytes and plasma. It is reversibly oxidised to dehydroascorbic acid; and metabolised to an inactive ascorbate-2-sulfate and oxalic acid which are excreted in the urine. Excess ascorbic acid (exceeding 100 mg daily) is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk.

Absorption of **zinc** from the gastrointestinal tract is incomplete, and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 % to 30%. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homeostasis. Small amounts are lost in urine and perspiration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicon dioxide
Maize starch
Talc
Magnesium stearate

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, containing a silica gel sachet and foam wadding.
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.