

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Magnesium Citrate 937,5 mg
(providing 150 mg elemental Magnesium)

ConcenTrace® (Trace Mineral Complex) 156 mg

(providing trace amounts of aluminium, antimony, barium, beryllium, bismuth, boron, bromine, cadmium, calcium, cerium, cesium, chloride, chromium, cobalt, copper, dysprosium, erbium, europium, fluoride, gadolinium, gallium, gold, hafnium, holmium, indium, iodine, iridium, iron, lanthanum, lead, lithium, lutetium, magnesium, manganese, mercury, molybdenum, neodymium, nickel, niobium, osmium, palladium, phosphorus, platinum, potassium, praseodymium, rhenium, rhodium, rubidium, ruthenium, samarium, scandium, selenium, silicon, silver, sodium, strontium, sulphate, tantalum, tellurium, terbium, thallium, thorium, thulium, tin, titanium, tungsten, vanadium, ytterbium, yttrium, zinc, zirconium)

Contains sugar: mannitol (196,25 mg) and sorbitol (170 mg) per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Large, oval-shaped tablet with a white film-coating.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS contributes to various functions in the body and towards the maintenance of good health.

4.2 Posology and method of administration

Adults and children 6 years and older:

Take one tablet daily.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Kidney disease reduces magnesium excretion and increases the risk for hypermagnesemia.

4.5 Interaction with other medicines and other forms of interaction

- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness. However, this is most likely to occur with high doses of magnesium given intravenously.
- Magnesium can decrease absorption of bisphosphonates, tetracyclines, quinolones and gabapentin.
- Magnesium salts may reduce absorption of digoxin and its therapeutic effects.
- Magnesium may precipitate ketamine toxicity.
- Magnesium can reduce the bioavailability of levodopa/carbidopa.
- Potassium-sparing diuretics also have magnesium-sparing properties, which decrease excretion of magnesium and possibly increasing magnesium levels.
- Magnesium increases systemic absorption of sulfonyleureas, increases their effects and side effects.

4.6 Fertility, pregnancy and lactation

Safety during 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+ MAGNESIUM & TRACE MINERALS does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: diarrhoea, gastrointestinal irritation, nausea, 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. 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>.

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 34.7 Minerals.

5.1 Pharmacodynamic properties

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS contributes to various functions in the body and towards the maintenance of good health.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Mannitol
Sorbitol
Polyvinylpyrrolidone
White film-coating

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

Amber glass bottle with a gold-coloured, child-resistant screw cap lid, packed into an outer carton.

Pack size: 30 tablets.

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
www.dischem.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

