

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 (providing 150 mg elemental Magnesium)	937,5 mg
ConcenTrace® (Trace Mineral Complex) (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)	156 mg

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 sulfonylureas, 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.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

SO

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

Complementary Medicine: Minerals (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Read all of this leaflet carefully because it contains important information for you.

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is and what it is used for.

2. What you need to know before you use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

3. How to use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

4. Possible side effects.

5. How to store DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

6. Contents of the pack and other information.

1. What DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is and what it is used for

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

2. What you need to know before you use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have a kidney disease.

Children and adolescents

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is not recommended for individuals below the age of 18 years.

Other medicines and DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use if you are taking any other medication, as DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS may alter their effectiveness. Consult a healthcare practitioner prior to use if you are taking any of the following medications: aminoglycoside antibiotics, bisphosphonates, tetracyclines, quinolones, gabapentin, digoxin, ketamine, levodopa/carbidopa, potassium-sparing diuretics, sulfonylureas.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

Driving and using machinery

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.

3. How to use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults 18 years and older

Take one tablet daily, or as recommended by your healthcare practitioner.

4. Possible side effects

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS can have side effects. Not all side effects reported for DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following: diarrhoea, gastrointestinal irritation, nausea, vomiting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

5. How to store DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

- Protect from moisture and store at or below 25 °C.

- KEEP OUT OF REACH OF CHILDREN.

- Store in the original container and keep the container tightly sealed.

- Do not use after the expiry date stated on the label.

- Return all unused DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS to your pharmacist.

- Do not dispose of unused DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS contains

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)

Other ingredients: magnesium stearate, mannitol, sorbitol, polyvinylpyrrolidone, white film-coating.

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

Presentation and identification of DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

Large, oval-shaped tablets with a white film-coating, in an amber glass bottle with a gold-coloured, child-resistant screw cap lid, packed into an outer carton.

Pack size: 30 tablets.

Holder of Certificate of Registration

Manufactured for: The Dis-Chem Group, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

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PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS
SO
DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS (filmbedekte tablette)
Komplementêre Medisyne: Minerale (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apoteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is en waarvoor dit gebruik word.

2. Wat u moet weet voordat u DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS gebruik.

3. Hoe om DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS te gebruik.

4. Hoe om DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS te bêre.

5. Inhoud van die verpakking en ander inligting.

1. **Wat DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is en waarvoor dit gebruik word**
DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS dra by tot verskeie funksies in die liggaam en tot die handhawing van goeie gesondheid.

2. **Wat u moet weet voordat u DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS gebruik**
'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal.

3. **Moenie DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS neem nie:**

- Indien u hypersensitief (allergies) is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voor dat u DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u 'n niersiekte het.

Kinders en adolessente

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS word nie aanbeveel vir individue onder die ouerdom van 18 jaar nie.

Die neem van DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige ander medisyne neem, aangesien DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS hul doeltreffendheid kan verander.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige van die volgende medisyne neem: aminoglykosid antibiotika, bisfosfonate, tetrasikliene, kinolone, gabapentien, digoksin, ketamien, levodopa/carbidopa, kaliumbesparende diuretika, sulfonylureas.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apoteker of ander gesondheidsorgpraktisyn vir advies voor dat u DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voor dat hulle bestuur van masjinerie gebruik, totdat hulle redelik seker is dat DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS nie hul werkverrigting nadruklik beïnvloed nie.

3. Hoe om DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS te gebruik

Moenie medisyne wat aan u voorgeskrif is met enige ander persoon deel nie. Moenie die aanbeveelde daagliks dosis oorskry nie. Gebruik DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volvassenes 18 jaar en ouer

Neem een tablet daagliks, of soos aanbeveel deur u gesondheidsorgpraktisyn.

4. Moontlike newe-effekte

DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS kan newe-effekte hê. Nie alle newe-effekte vir DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS is ingestel in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksieservaar tydens die gebruik van DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS, raadpleeg u dokter, apoteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS en raadpleeg u dokter of apoteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal:

- swelling van u hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk van asem te haal;
- veluitslag of gejeuk;
- floutes.

Hierdie is baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie op DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Sê vir u dokter indien u enige van die volgende opmerk: diarree, gastrointestinale irritasie, naarheid, brakking.

Lig asseblief u dokter of apoteker in indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuks genoem word nie.

Rapportering van newe-effekte

Praat met u dokter of apoteker as u newe-effekteervaar. U kan ook newe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS.

5. Hoe om DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS te bêre

- Beskerm teen vog en bêre by of onder 25 °C.

- HOU BIJTE BEREIK VAN KINDERS.

- Stoer in die oorspronklike verpakking en hou die houer dig verséel.

- Moenie gebruik na die vervaldatum op die etiket nie.

- Neem alle ongebruikte DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS na u apoteker terug.

- Neem die ongebruikte DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS in afvoersysteem (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS bevat

Elke tablet bevat:

Magnesiumstraat

937,5 mg

(verskaaf 150 mg elementale Magnesium)

156 mg

(verskaaf spoorhoeveelheid van aluminium, antimoon, barium, berillium, bismut, boor, broom, kadmium, kalsium, serum, sesium, chloried, chroom, kobalt, koper, dysprosium, erbium, europium, fluoried, gadolinium, gallium, goud, hafnium, holmium, indium, jodium, iridium, yster, lantaan, lood, lithium, lutetium, magnesium, mangaan, kwik, molibdeen, neodymium, nikkel, niobium, osmium, palladium, fosfor, platinum, kalium, praseodimum, renium, rhodium, rubidium, rutenum, samarium, skandium, selenium, silikon, silwer, natrium, strontium, sufaat, tantaal, telluur, terbium, thallium, torium, thulium, tin, titaan, wolfram, vanadium, ytterbium, yttrium, sink, sirkonium)

Ander bestanddele: magnesiumstearaat, mannitol, sorbitol, polivinylpirroldion, wit filmbedekking.

Bevat suiker: mannitol (196,25 mg) en sorbitol (170 mg) per tablet.

Anbieding en identifikasie van DIS-CHEM GOLD+ MAGNESIUM & TRACE MINERALS

Groot, ovaalvormige tablette met 'n wit filmbedekking, in 'n bruin glasbottel met 'n goudkleurige, kinderbestande skroefdop, verpak in 'n buitenste kartonhouer.

Verpakkingsgrootte: 30 tablete.

Houer van Registrasiesertifikaat

Vervaardig vir: The Dis-Chem Group, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 0860 347 243; careline@dischem.co.za; www.dischem.co.za

Hierdie pamphlet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.