

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 CALCIUM AND MAGNESIUM WITH BORON softgel capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each softgel capsule contains:

Calcium (as Calcium Carbonate)	300 mg
Magnesium (as Magnesium Oxide)	50 mg
Zinc (as Zinc Gluconate)	4 mg
Boron (as Boron Amino Acid Chelate)	1,5 mg
Manganese (as Manganese Sulphate)	1 mg
Copper (as Copper Bisglycinate)	0,5 mg
Folic Acid	100 µg
Cholecalciferol (Vitamin D3)	200 IU (5 µg)

Contains sugar: glycerol (0,12 g) and sorbitol (0,013 g) and maltodextrin (0,015 g) per softgel capsule.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Softgel capsules.

Oblong, black-brown coloured softgel capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON contains a combination of vitamins and minerals that assist with the development and maintenance of bones and teeth, and the maintenance of normal muscle function.

4.2 Posology and method of administration

Adults 18 years and older: one to two (1 – 2) softgel capsules daily.

Not recommended for individuals below the age of 18 years.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

A healthcare practitioner must be consulted prior to using DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON, especially in the case where the patient has a medical condition.

4.5 Interaction with other medicines and other forms of interaction

A healthcare practitioner must be consulted prior to using DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON if other medication (including complementary and traditional medicines) is being taken.

4.6 Fertility, pregnancy and lactation

Patients who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby must consult a healthcare practitioner for advice prior to using DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON.

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 CALCIUM AND MAGNESIUM WITH BORON does not adversely affect their performance.

4.8 Undesirable effects

Patients should inform their healthcare practitioner if they experience any of the following side effects, which may be indicative on a serious reaction to DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting.

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

5.1 Pharmacodynamic properties

Category and class: D 34.12 Multiple Substance Formulation.
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DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON contains a combination of vitamins and minerals that assist with the development and maintenance of bones and teeth, and the maintenance of normal muscle function.

5.2 Pharmacokinetic properties

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD CALCIUM AND MAGNESIUM WITH BORON.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunflower seed oil
Lecithin
Unsaturated oil
d- α -tocopherol (contains soya oil)
Gelatine (Bovine)
Glycerine
Purified water
Simethicone
Sorbitol 70%
Iron oxide black
Iron oxide red

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-coloured, child-resistant screw cap.

Pack size: 60 or 365 softgel capsules.

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, South Africa
0860 347 243
careline@dischem.co.za
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.