

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 CALCIUM PLUS coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Calcium (as Calcium Carbonate)	600 mg
Magnesium (as Magnesium Oxide)	50 mg
Zinc (as Zinc Oxide)	7,5 mg
Manganese (as Manganese Sulphate)	1,8 mg
Copper (as Copper Sulphate)	0,55 mg
Cholecalciferol (Vitamin D3)	12,5 µg (500 IU)

Contains sugar: sorbitol (97,3 mg) per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

White film-coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD CALCIUM PLUS contributes to the development and maintenance of strong bones and teeth. Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

4.2 Posology and method of administration

Adults 18 years and older:

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

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Consult with a healthcare practitioner prior to using DIS-CHEM GOLD CALCIUM PLUS, especially if you have a medical condition.

4.5 Interaction with other medicines and other forms of interaction

Consult a healthcare practitioner prior to use if you are taking any other medication, as DIS-CHEM GOLD CALCIUM PLUS may alter their effectiveness.

4.6 Fertility, pregnancy and lactation

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 CALCIUM PLUS.

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 PLUS does not adversely affect their performance.

4.8 Undesirable effects

DIS-CHEM GOLD CALCIUM PLUS can have side effects. Not all side effects reported for DIS-CHEM GOLD CALCIUM PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM GOLD CALCIUM PLUS, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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.

5.1 Pharmacodynamic properties

DIS-CHEM GOLD CALCIUM PLUS contributes to the development and maintenance of strong bones and teeth. Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD CALCIUM PLUS.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Magnesium stearate
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 and protect from sunlight and moisture.

6.5 Nature and contents of container

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

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.