PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulations. 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 PH BALANCE tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Calcium Carbonate†	300 mg
Calcium Amino Acid Chelate 20%†	100 mg
Calcium Hydroxide†	100 mg
Coral Calcium†	20 mg
†Providing elemental Calcium	214 mg
Sodium Bicarbonate	330 mg
Providing elemental Sodium	90 mg
Magnesium Carbonate	100 mg
Providing elemental Magnesium	29 mg
Boron Amino Acid Chelate 5%	6 mg
Providing elemental Boron	300 µg
Cholecalciferol (Vitamin D3)	2,5 µg (100 IU)

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oval-shaped, off-white tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Magnesium contributes to normal electrolyte balance. Calcium contributes to the normal function of digestive enzymes. Vitamin D assists the body in the utilisation of calcium.

4.2 Posology and method of administration

Adults 18 years and older: one (1) tablet up to three times daily.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

A healthcare practitioner must be consulted prior to using DIS-CHEM GOLD PH BALANCE, especially in the case where the patient has a medical condition.

Caution is advised in patients with hypercalcaemia, hypercalcuria, and/or kidney disease; hyperphosphataemia or hypophosphataemia; hypertension; and patients taking other supplements or medications that contain magnesium.

4.5 Interaction with other medicines and other forms of interaction

Patients who are taking other medication, including complementary or traditional medicines), should consult a healthcare practitioner prior to use.

DIS-CHEM GOLD PH BALANCE may interact with medications such as anticonvulsants, antiretrovirals, bisphosphonates, laxatives, diuretics, 4-quinolones, and tetracyclines.

4.6 Fertility, pregnancy and lactation

Patients who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby should consult a healthcare practitioner prior to using DIS-CHEM GOLD PH BALANCE.

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 PH BALANCE does not adversely affect their performance.

4.8 Undesirable effects

Frequent: nausea, constipation, flatulence.

Less frequent: hypercalcaemia.

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

Magnesium contributes to normal electrolyte balance. **Calcium** contributes to the normal function of digestive enzymes. **Vitamin D** assists the body in the utilisation of calcium.

5.2 Pharmacokinetic properties

Magnesium is absorbed from the small intestine after oral doses. Around one-third of magnesium is absorbed via the small intestine, but this fraction increases if magnesium intake decreases. In plasma, about 25 to 30% of magnesium is protein bound. Parenteral magnesium salts are excreted mainly in the urine, and oral doses are eliminated in the urine (absorbed fraction) and the faeces (unabsorbed fraction). Small amounts are distributed into breast milk. Magnesium crosses the placenta.

Calcium is absorbed mainly from the small intestine by active transport and passive diffusion. About one-third of ingested calcium is absorbed although this can vary depending upon dietary factory and the state of the small intestine; also absorption is increased in calcium deficiency during periods of high physiological requirement such as during childhood or pregnancy and lactation. Calcitriol, a metabolite of vitamin D, enhances the active phase of absorption. Excess calcium is mainly excreted renally. Unabsorbed calcium is eliminated in the faeces, together with that secreted in the bile and pancreatic juice. Minor amounts are lost in sweat, skin, hair and nails. Calcium crosses the placenta and is distributed into breast milk.

Sodium chloride is well absorbed from the gastrointestinal tract. Excess sodium is mainly excreted by the kidney, and small amounts are lost in the faeces and sweat.

Boron is rapidly absorbed, the mechanism of absorption from the gastrointestinal tract has not been elucidated. Boron is distributed throughout the body tissues; the highest concentrations are found in the bone, teeth, fingernails, spleen and thyroid. Boron is excreted mainly in the urine.

Vitamin D is well absorbed from the gastrointestinal tract with the aid of bile. Absorption may be decreased in patients with decreased fat absorption. Vitamin D and its metabolites circulate in the blood bound to a specific α-globulin. It is converted by hydroxylation, predominantly in the liver, to calcitriol, which is the main biologically active form of vitamin D. Small amounts are stored in the liver, as well as in adipose tissue. The metabolites of vitamin D analogues are excreted mainly in bile and faeces, with only small amounts appearing in urine. Although some vitamin D that is excreted in bile is reabsorbed in the small intestine, enterohepatic circulation does not appear to be an important mechanism for the conservation of the vitamin. Certain vitamin D substances may be distributed into breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium phosphate dibasic dehydrate
Polyvinylpyrrolidone
Maize starch
PVP solution 10%
Magnesium stearate
Silicone dioxide

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. KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

90 tablets packed into an amber glass bottle with a gold lid.

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.