

PROFESSIONAL INFORMATION

Complementary Medicine: Western Herbal Medicine

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 BRAIN & COGNITION vegetable capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

<i>Bacopa monnieri</i> L. (Bacopa)	160 mg
[whole plant, extract standardised to NLT	
20 % bacosides]	

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 0 white, vegetable capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD BRAIN & COGNITION may help to support healthy cognitive function.

4.2 Posology and method of administration

Adults 18 years and older:

Take two vegecapsules daily with breakfast, or as recommended by a healthcare practitioner.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Consult a healthcare practitioner prior to use if you suffer from:
 - bradycardia;
 - a gastrointestinal tract obstruction;
 - peptic ulcer disease;
 - a pulmonary condition such as asthma or chronic obstructive pulmonary disease;

- a thyroid disorder;
- a urogenital tract obstruction.

4.5 Interaction with other medicines and other forms of interaction

- Anticholinergic medications:** concurrent use with bacopa may decrease the effectiveness of both agents.
- Cevimeline:** bacopa may increase the effects and adverse effects of cevimeline.
- Cholinergic medications:** concurrent use of bacopa with other cholinergic medications may have additive effects.
- Thyroid hormone medications:** bacopa may have additive effects when use with thyroid hormone.

4.6 Fertility, pregnancy and lactation

Do not use if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

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 BRAIN & COGNITION does not adversely affect their performance.

4.8 Undesirable effects

Cardiovascular disorders

Frequency unknown: heart palpitations.

Gastrointestinal disorders

Frequency unknown: increased frequency of bowel movements, nausea, abdominal cramps, dry mouth, excessive thirst, indigestion, diarrhoea, flatulence, bloating, decreased appetite.

Musculoskeletal and connective tissues disorders

Frequency unknown: joint pain, muscle fatigue.

Nervous system disorders

Frequency unknown: drowsiness, headache, insomnia, vivid dreams, fatigue.

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.sahpра.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 33.6 Western Herbal Medicine.

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.

5.1 Pharmacodynamic properties

DIS-CHEM GOLD BRAIN & COGNITION may help to support healthy cognitive function.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD BRAIN & COGNITION.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Micrycrystalline cellulose
Magnesium stearate
Maize starch

Vegetable capsule shell:

Hypromellose

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 capsules.

6.6 Special precautions for disposal

No special requirements.