

PROFESSIONAL INFORMATION

Complementary Medicine: Combination Product

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 ADRENAL SUPPORT vegetable capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

| | |
|--|--------|
| <i>Panax ginseng</i> C.A. Mey. (Ginseng) [root, as 100 mg of a 5:1 extract] | 500 mg |
| Ascorbic Acid (Vitamin C) | 125 mg |
| <i>Rhodiola rosea</i> L. (Rhodiola) [root, extract standardised to 1 % salidrosides] | 100 mg |
| Vitamin B5 (as Calcium-d-Pantothenate) | 15 mg |
| Vitamin B6 (as Pyridoxine Hydrochloride) | 5 mg |
| Cyanocobalamin (Vitamin B12) | 20 µg |

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 ADRENAL SUPPORT helps to temporarily relieve symptoms of stress, supports cognitive function, such as mental focus and mental stamina, and enhances physical performance. It acts as an adaptogen to help increase energy and resistance to stress, such as stress-related mental and physical fatigue.

4.2 Posology and method of administration

Adults 18 years and older:

Take two vegecapsules daily, with or directly after breakfast, or as recommended by a healthcare practitioner. Consult a healthcare practitioner for use beyond three months or if symptoms persist or worsen.

Avoid taking before bedtime.

Not recommended for individuals below the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.
- Do not use DIS-CHEM GOLD ADRENAL SUPPORT if you have bipolar disorder or bipolar spectrum disorder.

4.4 Special warnings and precautions for use

- Consult a healthcare practitioner prior to use if you have:
 - diabetes;
 - an autoimmune disease;
 - a bleeding disorder;
 - a cardiovascular disease or disorder;
 - a hormone-sensitive cancer or condition;
 - insomnia;
 - schizophrenia.
- Consult a healthcare practitioner for use beyond three months.
- Consult a healthcare practitioner if symptoms persist or worsen while taking DIS-CHEM GOLD ADRENAL SUPPORT.

4.5 Interaction with other medicines and other forms of interaction

Consult a healthcare practitioner prior to use if you are taking any other medications, as DIS-CHEM GOLD ADRENAL SUPPORT may alter their effectiveness. Tell your doctor prior to using DIS-CHEM GOLD ADRENAL SUPPORT if you are taking any of the following:

- Antidepressants;
- Blood thinners;
- Digoxin;
- Hormone replacement therapy;
- Contraceptive medication;
- Diabetes medication;
- Antihypertensive medication;
- Immunosuppressants;
- Antiretroviral medication;
- P-glycoprotein substrates;
- Medications processed by the liver;
- Stimulants.

4.6 Fertility, pregnancy and lactation

Avoid 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 ADRENAL SUPPORT does not adversely affect their performance.

4.8 Undesirable effects

Discontinue use and tell your doctor as soon as possible if you notice any of the following:

- Insomnia;
- Anxiety;
- Headaches;
- Irritability;
- Increased or decreased saliva production;
- Dizziness;
- Euphoria;
- Mania;
- Vertigo;
- Amenorrhea;
- Postmenopausal vaginal bleeding.

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 33.7 Combination Product.

5.1 Pharmacodynamic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD ADRENAL SUPPORT helps to temporarily relieve symptoms of stress, supports cognitive function, such as mental focus and mental stamina, and enhances physical performance. It acts as an adaptogen to help increase energy and resistance to stress, such as stress-related mental and physical fatigue.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD ADRENAL SUPPORT.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Micrycrystalline cellulose
Magnesium stearate

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.

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.