

## 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 ASHWAGANDHA vegetable capsules

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegecapsule contains:

<i>Withania somnifera</i> L. (Ashwagandha) [root, as 200 mg of a 15:1 extract]	3000 mg
<i>Piper nigrum</i> L. (BioPerine®) [fruit, 50:1 extract standardised to 95 % piperine]	5 mg

Sugar free.

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Capsules.

Size 0 white, vegetable capsule containing a brown-green powder.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

DIS-CHEM GOLD ASHWAGANDHA acts as an adaptogen which may assist with increased levels of energy and resistance to stress.

#### 4.2 Posology and method of administration

##### Adults 18 years and older:

Take one to two vegecapsules, or as recommended by a healthcare practitioner.

Consult a health practitioner if symptoms persist or worsen.

Not recommended for individuals below the age of 18 years.

#### 4.3 Contraindications

- Hypersensitivity to ashwagandha 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 have an autoimmune disease or thyroid disorder.
- Consult a healthcare practitioner if symptoms persist or worsen.
- Discontinue use at least two weeks prior to any elective surgical procedures.

#### 4.5 Interaction with other medicines and other forms of interaction

The use of DIS-CHEM GOLD ASHWAGANDHA together with alcohol or medicines that cause drowsiness (e.g. benzodiazepines and CNS depressants) should be avoided.

#### 4.6 Fertility, pregnancy and lactation

Safety for use during fertility, pregnancy and lactation has not been established.

#### 4.7 Effects on ability to drive and use machines

DIS-CHEM GOLD ASHWAGANDHA may make you feel drowsy or sleepy. Exercise caution if operating heavy machinery, driving a motor vehicle or for activities requiring mental alertness.

#### 4.8 Undesirable effects

##### Gastrointestinal disorders

*Frequency unknown:* nausea, abdominal pain, gastritis, flatulence.

##### Nervous system disorders

*Frequency unknown:* drowsiness.

#### 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 33.6 Western Herbal Medicine.

**5.1 Pharmacodynamic properties**

DIS-CHEM GOLD ASHWAGANDHA acts as an adaptogen which may assist with increased levels of energy and resistance to stress.

**5.2 Pharmacokinetic properties**

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

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

***Capsule contents:***

Micrycrystalline cellulose  
Magnesium stearate  
Maize starch  
Silicon dioxide

***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, containing a silica gel sachet and foam wadding.  
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.