

## 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 HAIR, SKIN & NAILS softgel capsules

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each softgel contains:

Hydrolysed Collagen	75 mg
Calcium-d-pantothenate (Vitamin B5)	25 mg
Nicotinamide (Vitamin B3)	20 mg
Ascorbic Acid (Vitamin C)	20 mg
Zinc (as Zinc Oxide)	10 mg
L-Cysteine (as L-Cysteine Hydrochloride)	10 mg
d- $\alpha$ -Tocopherol (Vitamin E)	5,4 mg $\alpha$ -TE
Co-Enzyme Q10	5 mg
Copper (as Copper Amino Acid Chelate)	0,45 mg
Biotin (Vitamin H)	400 $\mu$ g
Folic Acid	400 $\mu$ g
Selenium (as Selenium Amino Acid Chelate)	50 $\mu$ g
Cyanocobalamin (Vitamin B12)	25 $\mu$ g
Iodine (as Potassium Iodide)	14 $\mu$ g

Contains sugar: 0,06 g glycerol, 0,008 g sorbitol, and 0,03 g mannitol/maltodextrin per softgel capsule.

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Cherry-brown coloured, oval softgel capsules.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

DIS-CHEM GOLD HAIR, SKIN & NAILS contains a combination of vitamins and minerals which contribute to the maintenance of normal hair, skin and nails.

##### 4.2 Posology and method of administration

Adults 18 years and older: one (1) softgel capsule daily.

Consult a healthcare practitioner prior to use for individuals under the age of 18 years.

##### 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 HAIR, SKIN & NAILS, especially in the case where the patient has a medical condition.

##### 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.

##### 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 HAIR, SKIN & NAILS.

##### 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 HAIR, SKIN & NAILS does not adversely affect their performance.

##### 4.8 Undesirable effects

Patients should inform their healthcare practitioner if they experience any of the following side effects, which may be indicative on a serious reaction to DIS-CHEM GOLD L-CYSTEINE: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting.

##### 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**

DIS-CHEM GOLD HAIR, SKIN & NAILS contains a combination of vitamins and minerals which contribute to the maintenance of normal hair, skin and nails.

#### **5.2 Pharmacokinetic properties**

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD HAIR, SKIN & NAILS.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Sunflower seed oil  
Colloidal anhydrous silica  
Glycerol monostearate  
Purified water  
Glycerine  
Simethicone  
Gelatine  
Iron oxide black  
Iron oxide red  
Sorbitol 70%

#### **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**

30/60 softgel capsules 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](http://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.