

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-α-Tocopherol (Vitamin E)	5,4 mg α-TE
Co-Enzyme Q10	5 mg
Copper (as Copper Amino Acid Chelate)	0,45 mg
Biotin (Vitamin H)	400 µg
Folic Acid	400 µg
Selenium (as Selenium Amino Acid Chelate)	50 µg
Cyanocobalamin (Vitamin B12)	25 µg
Iodine (as Potassium Iodide)	14 µg

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

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.