

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

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 BIOTIN 500 µg coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Biotin (Vitamin H)	500 µg
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Contains sugar: lactose (589 mg) per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Oval, light-purple (lilac) film-coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIS-CHEM GOLD BIOTIN 500 µg contributes to the maintenance of normal hair and skin, the metabolism of carbohydrates, fats and proteins, and towards the normal function of the nervous system.

4.2 Posology and method of administration

Adults and children 6 years and older:

Take one tablet daily, or as recommended by a healthcare practitioner.

Not recommended for individuals below the age of 6 years.

4.3 Contraindications

- Hypersensitivity to biotin 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 biotinidase deficiency;
 - are a tobacco smoker;
 - are receiving renal dialysis.

4.5 Interaction with other medicines and other forms of interaction

Consult a healthcare practitioner prior to use if you are taking any other medication, as DIS-CHEM GOLD BIOTIN 500 µg may alter their effectiveness.

4.6 Fertility, pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using DIS-CHEM GOLD BIOTIN 500 µg.

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 BIOTIN 500 µg does not adversely affect their performance.

4.8 Undesirable effects

DIS-CHEM GOLD BIOTIN 500 µg can have side effects. Not all side effects reported for DIS-CHEM GOLD BIOTIN 500 µg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIS-CHEM GOLD BIOTIN 500 µg, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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 34.11 Vitamins.

5.1 Pharmacodynamic properties

DIS-CHEM GOLD BIOTIN 500 µg contributes to the maintenance of normal hair and skin, the metabolism of carbohydrates, fats and proteins, and towards the normal function of the nervous system.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on DIS-CHEM GOLD BIOTIN 500 µg.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Talc
Lactose
Magnesium stearate
Croscarmellose sodium
Film-coating

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 tablets.

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.