

## PROFESSIONAL INFORMATION

### 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 BIOTIN 500 µg film-coated tablets

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Biotin (Vitamin H) 500 µg

Contains sugar (589 mg lactose per tablet)

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Tablets.  
Light purple (lilac), oval 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. It helps the body metabolise carbohydrates, fats and proteins. It also contributes to the normal functioning of the nervous system.

##### 4.2 Posology and method of administration

Adults and children 6 years and older: One (1) tablet daily.

##### 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

- Patients with an existing medical condition must consult a healthcare practitioner prior to use.

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

- Requirements for biotin may be increased in patients who are taking anticonvulsants (carbamazepine, phenobarbitone, phenytoin and primidone).

##### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

##### 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

There are no reported side-effects associated with the use of DIS-CHEM GOLD BIOTIN 500 µg. Patients who's general health worsens or who experiences any untoward effects while taking this medicine should inform their doctor or other registered healthcare practitioner.

##### 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. Complementary Medicine: Health Supplement.

### 5.1 Pharmacodynamic properties

**Biotin** contributes to the maintenance of normal hair and skin. It helps the body metabolise carbohydrates, fats and proteins. It also contributes to the normal functioning of the nervous system.

### 5.2 Pharmacokinetic properties

Biotin is completely absorbed after oral administration and

reaches peak concentration after 1 – 2 hours. Biotin is transported across the intestinal lumen enterocytes by sodium-dependent multivitamin transporter (SMVT) and into the liver and peripheral tissues. SMVT also mediates renal reabsorption of biotin. Biotin metabolites are formed by beta-oxidation, sulphur oxidation, or both. About half of the dose of biotin is excreted within 24 hours. Biotin is excreted in the urine as unmetabolized biotin or as biotin metabolites. Biotin is recycled endogenously.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Microcrystalline cellulose  
Talc  
Lactose  
Magnesium stearate  
Crosscarmellose sodium  
Flexicoat coating solution

### **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.

### **6.5 Nature and contents of container**

Glass amber bottle with a gold child-resistant screw cap, containing a silica gel sachet.  
Pack size: 60 film-coated 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, Johannesburg, South Africa  
careline@dischem.co.za  
0860 347 243

## **8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

## **9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.