

PATIENT INFORMATION LEAFLET

COMPLEMENTARY MEDICINE HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS:

S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Biogen
FOR THE RESULTS YOU WANT

BIOTIN

(capsules)

Read this entire leaflet carefully because it contains important information for you.

BIOGEN BIOTIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **BIOGEN BIOTIN** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **BIOGEN BIOTIN** with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT BIOGEN BIOTIN CONTAINS:

Each capsule contains:

Biotin 500 µg

The other ingredients are maize starch, silicon dioxide, magnesium stearate, bovine capsule, fine salt.

Sugar free.

2. WHAT BIOGEN BIOTIN IS USED FOR:

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

3. BEFORE YOU TAKE BIOGEN BIOTIN:

Do not take BIOGEN BIOTIN:

- If you are hypersensitive (allergic) to **BIOTIN** or any of the other ingredients of **BIOGEN BIOTIN** (see **WHAT BIOGEN BIOTIN CONTAINS**).

Take special care with BIOGEN BIOTIN:

- Seek advice from a health care practitioner if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Taking BIOGEN BIOTIN with food and drink:

- **BIOGEN BIOTIN** can be taken with or without food.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **BIOGEN BIOTIN**.

Taking other medicines with BIOGEN BIOTIN:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) **BIOTIN** might increase how quickly the liver breaks down some medications.

Taking **biotin** along with some medications that are processed by the liver might decrease the effects of some of these medications. Some of these medications include clozapine (Clozaril), cyclobenzaprine (Flexeril), fluvoxamine (Luvox), haloperidol (Haldol), imipramine (Tofranil), mexiletine (Mexitil), olanzapine (Zyprexa), pentazocine (Talwin), propranolol (Inderal), tacrine (Cognex), theophylline, zileuton (Zyflo), zolmitriptan (Zomig), and others. Before taking **biotin**, talk to your healthcare provider if you take any medications that are processed by the liver.

4. HOW TO TAKE BIOGEN BIOTIN:

- The usual dose is 1 capsule daily, or as recommended by a healthcare practitioner.
- If you have the impression that the effect of **BIOGEN BIOTIN** is too strong or too weak, tell your doctor or pharmacist.

If you take more BIOGEN BIOTIN than you should:

In the event of an over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining **BIOGEN BIOTIN** with you so the doctor will know what you have taken.

5. POSSIBLE SIDE EFFECTS:

- There are no reported side-effects associated with the use of **BIOGEN BIOTIN**. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care practitioner for advice.

6. STORING AND DISPOSING OF BIOGEN BIOTIN:

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Protect from moisture and store at or below 25 °C.
- Store in original packaging until required for use.
- Do not use after the expiry date printed on the container.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- Return all unused medicine to your pharmacist.

7. PRESENTATION OF BIOGEN BIOTIN:

175 mL white PET bottle with a screw cap, heat seal, sponge and silica.
Pack size: 30 capsules.

8. IDENTIFICATION OF BIOGEN B-COMPLEX BURST:

White to off-white powder in a size 1 white bovine gelatine capsule.

9. REGISTRATION NUMBER:

Will be allocated by SAHPRA upon registration.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

11. DATE OF PUBLICATION:

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAADJIE

AANVULLENDE MEDISYNE GESONDHEIDSAANVULLING

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

SKEDULERINGSSTATUS:

S0

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:

Biogen
FOR THE RESULTS YOU WANT

BIOTIN

(kapsules)

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

BIOGEN BIOTIN is beskikbaar sonder 'n dokter se voorskrif, sodat u 'n ligte aandoening kan behandel. U moet **BIOGEN BIOTIN** nietermin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie **BIOGEN BIOTIN** met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies nodig het.

1. WAT BIOGEN BIOTIN BEVAT:

Elke kapsule bevat:

Biotien 500 µg

Die ander bestanddele is Melie stysel, silikondioksied, magnesiumstearaat, en beesgelatien kapsule, fyn sout.

Sugarvry.

2. WAARVOOR BIOGEN BIOTIN GEBRUIK WORD:

Biotien dra by tot die instandhouding van normale hare en vel. Dit help die liggaam om koolhidrate, vette en proteïene te metaboliseer. Dit dra ook by tot die normale werking van die senuweestelsel.

3. VOORDAT U BIOGEN BIOTIN NEEM:

Moenie BIOGEN BIOTIN neem nie:

- Indien u hipersensitief (allergies) vir **Biotien** of vir enige van die ander bestanddele van **BIOGEN BIOTIN** (sien **WAT BIOGEN BIOTIN BEVAT**).

Wees versigtig met BIOGEN BIOTIN:

- Raadpleeg 'n gesondheidspraktisyn indien u enige mediese toestand het. Staak gebruik onmiddellik as enige negatiewe reaksie voorkom.

Die neem van BIOGEN BIOTIN met kos en drinkgoed:

- **BIOGEN BIOTIN** kan met of sonder kos geneem word.

Swangerskap en borsvoeding:

- Indien u swanger is of u baba borsvoed, raadpleeg asseblief u gesondheidsorgverskaffer voordat u **BIOGEN BIOTIN** neem.

Die neem van ander medisyne saam met BIOGEN BIOTIN:

Sê altyd vir u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in.) **Biotien** kan die spoed verhoog waar teen die lewer sommige medikasies afbreek.

Die gelyktydige inname van **biotien** en sommige medisyne kan die effektiwiteit van sodanige medisyne verminder. Sommige van hierdie medisyne sluit clozapien (Clozaril), siklobenzaprien (Flexeril), fluvoxamien (Luvox), haloperidol (Haldol), imipramien (Tofranil), mexiletien (Mexitil), olanzapien (Zyprexa), pentasocien (Talwin), propranolol (Inderal), tacrine (Cognex), teofyllien, zileuton (Zyflo), zolmitriptan (Zomig), en ander in. Voordat u **biotien** neem, praat met u gesondheidsorgpraktisyn indien u medisyne neem wat deur die lewer verwerk word.

4. HOE OM BIOGEN BIOTIN TE NEEM:

- Die gebruikelike dosis is 1 kapsule daaglik, of soos aanbeveel deur u gesondheidsorgpraktisyn.
- Indien u die indruk kry dat die effek van **BIOGEN BIOTIN** te sterk of swak is, vertel u dokter of apteker daarvan.

Indien u meer BIOGEN BIOTIN neem as wat u behoort:

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die houer met die oorblywende **BIOGEN BIOTIN** saam met u, sodat die dokter kan sien wat u geneem het.

5. MOONTLIKE NEWE-EFFEKTE:

- Geen nuwe-effekte wat verband hou met die gebruik van die **BIOGEN BIOTIN** is sover aangemeld nie. Indien u algemene gesondheid versleg, of indien u enige ongewenste reaksie toon terwyl u die medisyne gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgpraktisyn.

6. BERGING EN WEGDOENING VAN BIOGEN BIOTIN BURST:

- HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS
- Beskerm teen vog en stoor by of onder 25 °C.
- Stoor in die oorspronklike houer tot nodig vir gebruik
- Moenie gebruik word na die vervaldatum nie.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
- Neem alle ongebruikte medisyne terug na u apteker.

7. AANBIEDING VAN BIOGEN BIOTIN:

175 mL wit PET-bottel met 'n skroefprop, hittedeël, spons en silika.
Verpakkingsgrootte: 30 kapsules.

8. IDENTIFIKASIE VAN BIOGEN BIOTIN:

Wit tot naaswit poeier in 'n grootte 1 wit beesgelatien kapsule.

9. REGISTRASIE-NOMMER:

Sal met registrasie deur SAHPRA toegeken word.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Biogen
Stag Weg 23, Glen Austin, Suid Afrika
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

11. DATUM VAN PUBLIKASIE:

Sal met registrasie deur SAHPRA toegeken word.

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

PROPRIETARY NAME AND DOSAGE FORM:

BIOGEN
FOR THE RESULTS YOU WANT

BIOTIN

(capsules)

COMPOSITION:

Each capsule contains:
Biotin / Biotien

500 µg

EXCIPIENTS: Maize starch, silicon dioxide, magnesium stearate, bovine capsule, fine salt.

Sugar free

CATEGORY AND CLASS:

Category D 34.11 Vitamins.

Complementary Medicine: Health Supplements.

PHARMACOLOGICAL ACTION:

BIOGEN BIOTIN is a water-soluble vitamin and is also known as Vitamin H or Vitamin B₇. **BIOGEN BIOTIN** functions as a coenzyme for reactions involving the addition or removal of carbon dioxide to or from active compounds. It promotes the production of glucose, fatty acids, and DNA, and it helps to break down amino acids. Orally, **BIOGEN BIOTIN** is used for preventing and treating biotin deficiency associated with pregnancy, long-term parenteral nutrition, malnutrition, rapid weight loss and multiple carboxylase deficiency. It is also used orally for hair loss and brittle nails.

INDICATIONS:

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

CONTRAINDICATIONS:

Avoid in people with known allergy or sensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

- Seek advice from a health care practitioner if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

INTERACTIONS:

- Always tell your healthcare professional if you are taking any other medicine.
- **BIOGEN BIOTIN** might increase how quickly the liver breaks down some medications.
- Taking **BIOGEN BIOTIN** along with some medications that are processed by the liver might decrease the effects of some of these medications. Some of these medications include clozapine (Clozaril), cyclobenzaprine (Flexeril), fluvoxamine (Luvox), haloperidol (Haldol), imipramine (Tofranil), mexiletine (Mexitil), olanzapine (Zyprexa), pentazocine (Talwin), propranolol (Inderal), tacrine (Cognex), theophylline, zileuton (Zyflo), zolmitriptan (Zomig), and others.
- Before taking **BIOGEN BIOTIN**, talk to your healthcare provider if you take any medications that are processed by the liver.

HUMAN REPRODUCTION:

- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children older than 12 years:

Take one capsule daily, or as recommended by your health care professional. Inform your doctor if you are taking any other medication. Do not exceed the daily recommended dose. Do not share medicines prescribed for you with any other person. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE EFFECTS:

There are no reported side-effects associated with the use of **BIOGEN BIOTIN**.

Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care practitioner for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **SIDE EFFECTS**.

Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

IDENTIFICATION:

White to off-white powder in a size 1 white bovine capsule.

PRESENTATION:

175 mL white PET bottle with a screw cap, heat seal, sponge and silica.
Pack size: 30 capsuless.

STORAGE INSTRUCTIONS:

Protect from moisture and store at or below 25 °C.
Keep tablets in original container until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Will be allocated by SAHPRA upon registration.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Will be allocated by SAHPRA upon registration.

