local health
Your Life / Your Choice

BIOTIN

SCHEDULING STATUS: S0

PATIENT INFORMATION LEAFLET

LOCAL HEALTH BIOTIN (Tablets)
Biotin (Vitamin H).

Sugar Free.

Complementary Medicine: D.34.11 Vitamins
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this insert carefully as it contains important information for you.
LOCAL HEALTH BIOTIN is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH BIOTIN carefully to get the best results from it.
- Keep this leaflet, you may need it again.
- Do not share LOCAL HEALTH BIOTIN with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet
- What LOCAL HEALTH BIOTIN is and what it is used for.
- What you need to know before you take LOCAL HEALTH BIOTIN.
- How to take LOCAL HEALTH BIOTIN.
- Possible side effects.
- How to store LOCAL HEALTH BIOTIN.
- Contents of the pack and other information.

1.What LOCAL HEALTH BIOTIN is and what it is used for.
LOCAL HEALTH BIOTIN is a vitamin supplement that:
- Supports the normal functioning of the nervous system, helps maintain healthy hair and skin, and plays a key role in the overall maintenance of good health.

2. What you need to know before you use LOCAL HEALTH BIOTIN.
Do not take LOCAL HEALTH BIOTIN:
- If you are hypersensitive (allergic) to the active ingredients or any of the other ingredients of LOCAL HEALTH BIOTIN (listed in section 6).

Warnings and precautions
Take special care:
- If you have anaemia, liver or metabolism problems.

Children and adolescents
LOCAL HEALTH BIOTIN is suitable for adults and children 6 years and older. Consult with your healthcare practitioner before using.

Other medicine and LOCAL HEALTH BIOTIN
Always tell your healthcare practitioner if you are taking any other medicine. This includes complementary or traditional medicines. Not all possible interactions with other medicine may be included in this leaflet. Consult with your healthcare practitioner prior to use. LOCAL HEALTH BIOTIN has no known interaction with other medicine if taken at recommended daily dosage.

LOCAL HEALTH BIOTIN with food and drink
No known interaction with food and drinks. See Section 3.

Pregnancy, breastfeeding and fertility
If you are pregnant, planning to become pregnant, or are breastfeeding please consult your doctor, pharmacist or healthcare practitioner before using LOCAL HEALTH BIOTIN. Safety in pregnancy has not been established.

Driving and the use of machinery
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 LOCAL HEALTH BIOTIN does not adversely affect their performance.

3. How to use LOCAL HEALTH BIOTIN.
Do not share your medicines with any other person.
Always give LOCAL HEALTH BIOTIN exactly as prescribed in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.
Adults and Children 6 years and older
Take one tablet daily or as recommended by your healthcare practitioner.
Do not exceed the recommended daily dosage.

4. Possible side effects.
LOCAL HEALTH BIOTIN can have side effects.
Not all side effects reported for LOCAL HEALTH BIOTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH BIOTIN please consult your healthcare practitioner for advice.

If any of the following happens, stop using LOCAL HEALTH BIOTIN and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH BIOTIN. You may need urgent medical attention or hospitalisation.
Tell your doctor if you notice any of the following:
- abdominal pain,
- dyspepsia (indigestion),
- bloating,
- diarrhoea,
- rash,
- fatigue,
- headache,
- vertigo.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:
If you are experiencing side effects, inform your doctor or pharmacist. You can also report your side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Form"** found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side-effects you can help provide more information on the safety of LOCAL HEALTH BIOTIN.

5. How to store LOCAL HEALTH BIOTIN.
- Store at or below 25 °C in a dry place away from moisture and direct sunlight.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original packaging until required for use.
- Do not use after expiry date on the label.
- Return all unused LOCAL HEALTH BIOTIN to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information
What LOCAL HEALTH BIOTIN contains

Each tablet contains:
Biotin (Vitamin H) 500 µg

The other ingredients are Dicalcium Phosphate, Microcrystalline Cellulose, Magnesium Stearate.

Sugar free

Presentation and identification of LOCAL HEALTH BIOTIN
White round tablets packed into a white PET 175 ml container with a white screw-cap lid.
Pack size: 30 tablets.

Holder of certificate of Registration
Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685.
Careline: 010 589 2729; careline@cjdsa.com; **www.localhealth.co.za**

This pamphlet was last revised in
October 2024

Registration number
Will be allocated by SAHPRA upon registration.

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BIOTIN

SKEDULERINGS STATUS: S0

PASIËNTINLIGTINGSBLAD

LOCAL HEALTH BIOTIN (Tablette)
Biotien (Vitamien H).

Suikervry.

Komplementêre Medisyne: D.34.11 Vitamiene
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

Lees hierdie inligtingspamflet deeglik deur aangesien dit belangrike inligting vir jou bevat.
LOCAL HEALTH BIOTIN is beskikbaar sonder 'n dokter se voorskrif om jou gesondheid te handhaaf.
Nietemin moet jy LOCAL HEALTH BIOTIN steeds versigtig gebruik om die beste resultate te kry.
- Hou hierdie pamflet, jy mag dit weer nodig hê.
- Moet nie LOCAL HEALTH BIOTIN met enige ander persoon deel nie.
- Vra jou gesondheidsorgpraktisyn of apteker indien jy meer inligting of advies benodig.

Wat is in hierdie inligtingsblad
- Wat LOCAL HEALTH BIOTIN is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy LOCAL HEALTH BIOTIN gebruik.
- Hoe om LOCAL HEALTH BIOTIN te gebruik.
- Moontlike newe-effekte.
- Hoe om LOCAL HEALTH BIOTIN te bêre.
- Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH BIOTIN is en waarvoor dit gebruik word.
LOCAL HEALTH BIOTIN is 'n vitamienaanvulling wat:
- Die normale funksionering van die senuweestelsel ondersteun, help om gesonde hare en vel te handhaaf, en 'n sleutelrol speel in die algehele instandhouding van goeie gesondheid.

2. Wat jy moet weet voordat jy LOCAL HEALTH BIOTIN gebruik.
Moet nie LOCAL HEALTH BIOTIN neem nie:
• As jy hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van LOCAL HEALTH BIOTIN (gelys in afdeling 6).
Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg:
- As jy bloedarmoede, lewer- of metabolismeprobleme het.

Kinders en adolessente
LOCAL HEALTH BIOTIN is geskik vir volwassenes en kinders 6 jaar en ouer. Raadpleeg jou gesondheidsorgpraktisyn voordat jy dit gebruik.

Ander medisyne en LOCAL HEALTH BIOTIN
Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne neem. Dit sluit komplementêre of tradisionele medisyne in. Nie alle moontlike interaksies met ander medisyne is in hierdie pamflet ingesluit nie. Raadpleeg jou gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH BIOTIN het geen bekende interaksie met ander medisyne indien dit teen die aanbevole daaglikse dosis geneem word nie.

LOCAL HEALTH BIOTIN met kos en drinkgoed
Geen bekende interaksie met kos en drinkgoed nie. Sien Afdeling 3.

Swangerskap, borsvoeding en vrugbaarheid
As jy swanger is, beplan om swanger te raak, of borsvoed, raadpleeg asseblief jou dokter, apteker of gesondheidsorgpraktisyn voordat jy LOCAL HEALTH BIOTIN gebruik. Veiligheid tydens swangerskap is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Geen studies oor die effekte op bestuur of die gebruik van masjinerie is uitgevoer nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat LOCAL HEALTH BIOTIN nie hul prestasie negatief beinvloed nie.

3. Hoe om LOCAL HEALTH BIOTIN te gebruik.
Moet nie medisyne wat vir jou voorgeskryf is met ander persone deel nie.
Gebruik altyd LOCAL HEALTH BIOTIN presies soos in hierdie pamflet voorgeskryf of soos jou gesondheidsorgpraktisyn jou aangesê het. Raadpleeg jou gesondheidsorgpraktisyn indien jy onseker is.
Volwassenes en Kinders 6 jaar en ouer
Neem 1 tablet daagliks of soos aangedui deur 'n gesondheidsorgpraktisyn.
Moenie die aanbevole dosis oorskry nie.

4. Moontlike newe-effekte.
LOCAL HEALTH BIOTIN kan newe-effekte hê.
Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, is in hierdie pamflet ingesluit nie. As jou algemene gesondheid versleg of jy enige ongewensde effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou gesondheidsorgpraktisyn vir advies.

Indien jy enige van die volgende ervaar, hou op om LOCAL HEALTH BIOTIN te neem en sê dadelik vir jou dokter of apteker, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat sukkel met sluk of asemhaling kan veroorsaak;
- uitslag of jeuk;
- floutes.

Dit is baie ernstige newe-effekte. As jy hulle ervaar, kan jy 'n ernstige reaksie op LOCAL HEALTH BIOTIN hê. Jy mag dringende mediese aandag of hospitalisasie benodig.
Sê vir jou dokter as jy enige van die volgende opmerk:
- buikpyn,
- dispepsie (indigestie),
- opgeblasenheid,
- diarree,
- uitslag,
- moegheid,
- hoofpyn,
- lighoofdigheid.

As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte:
As jy enige newe-effekte ervaar, lig asseblief jou dokter of apteker in. Jy kan ook jou newe-effekte aan SAHPRA rapporteer deur die **"6.04 Adverse Drug Reaction Form"** wat aanlyn beskikbaar is onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van LOCAL HEALTH BIOTIN te verskaf.

5. Berging van LOCAL HEALTH BIOTIN.
- Beskerm teen vog en bêre teen of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum op die etiket nie.
- Stuur alle ongebruikte LOCAL HEALTH BIOTIN terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting.
Wat LOCAL HEALTH BIOTIN bevat

Elke tablet bevat:
Biotien (Vitamien H) 500 µg

Die ander bestanddele is Dikalsiumfosfaat, Mikrokristallyne Sellulose, Magnesiumstearaat.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH BIOTIN.
Wit ronde tablette verpak in 'n wit PET 175 ml houer met 'n wit skroefdop.
Verpakkingsgrootte: 30 tablette.

Houer van Registrasiesertifikaat:
CJ Distribution, 23 Stagweg, Glen Austin, Johannesburg, Suid-Afrika, 1685.
Kliëntediens: 010 589 2729; careline@cjdsa.com; **www.localhealth.co.za**

Hierdie pamflet is laas hersien in
Oktober 2024

Registrasienommer:
Sal met registrasie deur SAHPRA toegeken word.

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BIOTIN

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: D.34.11 VITAMINS
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0
1.NAME OF THE MEDICINE
LOCAL HEALTH BIOTIN (Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Biotin (Vitamin H) 500 µg

Sugar free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Tablets.
White round tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
LOCAL HEALTH BIOTIN is a vitamin supplement that:
- Supports the normal functioning of the nervous system, helps maintain healthy hair and skin, and plays a key role in the overall maintenance of good health.

4.2 Posology and method of administration
Posology
Adults and Children 6 years and older: Take one tablet daily or as recommended by your healthcare practitioner. Do not exceed the recommended daily dosage.

Method of administration
For oral use.

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 to use
Take special care:
- If you have anaemia, liver or metabolism problems.
- Vitamin supplements should not replace a balanced diet.

4.5 Interactions
Biotin
None known at recommended daily dosages.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines
LOCAL HEALTH BIOTIN studies on the ability to drive or use machinery have not been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH BIOTIN does not adversely affect their performance.

4.8 Undesirable effects
LOCAL HEALTH BIOTIN is generally well tolerated.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefits/risk balance of the medicine. healthcare practitioners are asked
to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/8.

4.9 Overdose
In the event of an overdose, undesirable effects listed in 4.8 can be precipitated or be of increased severity. Treatment is supportive and symptomatic. Should accidental overdose occur, discontinue use and consult a doctor or pharmacist.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
- **Biotin:** Supports the maintenance of normal hair, skin, and nails, as well as energy-yielding metabolism.

5.2 Pharmacokinetic properties
- **Biotin:** Absorbed in the small intestine, distributed in plasma, and excreted via urine.

6.1 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Dicalcium Phosphate, Microcrystalline Cellulose, Magnesium Stearate.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months.

6.4 Special precaution for storage
Store at or below 25 °C. Store in the original packaging in order to protect from moisture.

6.5 Nature and contents of container
White 175 ml PET container with white screwcap lid.
Pack size: 30 tablets

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@cjdsa.com
010 589 2729
www.localhealth.co.za

8 REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.