PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX BIOTIN 500mcg hard capsules

Biotin (vitamin B7) 500 micrograms per daily dose (1 capsule)
Sugar free

COMPLEMENTARY MEDICINE
Health Supplement
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet is also available in Afrikaans at https://genologix.co.za/product/genologix-biotin-500mcg-bulk-120-days-supply/

Read all of this leaflet carefully because it contains important information for you

Genologix Biotin 500mcg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Biotin 500mcg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Biotin 500mcg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Genologix Biotin 500mcg is and what it is used for
2. What you need to know before you take Genologix Biotin 500mcg
3. How to take Genologix Biotin 500mcg
4. Possible side effects
5. How to store Genologix Biotin 500mcg
6. Contents of the pack and other information

1. What Genologix Biotin 500mcg is and what it is used for

Genologix Biotin 500mcg is a health supplement. It contains biotin, also called vitamin B7.

Genologix Biotin 500mcg:

- contributes to the maintenance of normal hair;
- contributes to the maintenance of normal skin;
- contributes to normal energy-yielding metabolism;
- helps the body to metabolise carbohydrates, fats and proteins; and
- is a factor in the maintenance of good health.

2. What you need to know before you take Genologix Biotin 500mcg

Do not take Genologix Biotin 500mcg:

- if you are hypersensitive (allergic) to biotin or any of the other ingredients of Genologix Biotin 500mcg (listed in section 6).

Warnings and precautions

Take special care with Genologix Biotin 500mcg. Talk to your doctor or pharmacist before taking it:

- if you are going to have a blood test. Biotin can give false results in some laboratory tests, including tests for thyroid function and heart attacks (troponin). Tell your doctor or the laboratory staff that you take biotin. You may need to stop taking it for a few days before the test; or
- if you take any medicine prescribed by your doctor.

Biotin from other supplements (such as multivitamins or hair, skin and nail products) should be taken into account when taking Genologix Biotin 500mcg.

Children and adolescents

Do not give Genologix Biotin 500mcg to children and adolescents under 18 years of age. Its safety in this age group has not been established.

Other medicines and Genologix Biotin 500mcg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines for epilepsy (e.g. carbamazepine, phenytoin, phenobarbital and primidone) may lower biotin levels in the body.

Biotin can interfere with some laboratory blood tests (see “Warnings and precautions”).

Genologix Biotin 500mcg with food, drink and alcohol

Take Genologix Biotin 500mcg with food (see section 3). Eating large amounts of raw egg whites can reduce how much biotin your body absorbs.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, consult your health care provider before taking Genologix Biotin 500mcg.

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 health care provider for advice before taking this medicine.

Driving and using machines

Genologix Biotin 500mcg is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Biotin 500mcg may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Biotin 500mcg affects you.

Genologix Biotin 500mcg contains

Genologix Biotin 500mcg contains no sugar and no sweeteners.

3. How to take Genologix Biotin 500mcg

Do not share medicines prescribed for you with any other person.

Always take Genologix Biotin 500mcg exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (18 years and older): take one (1) capsule a day. This provides 500 micrograms of biotin.

Do not take more than one (1) capsule in 24 hours.

Children and adolescents under 18 years: Genologix Biotin 500mcg is not intended for this age group.

How to take it:

1. Take the capsule during the day, with food.
2. Swallow the capsule whole with a glass of water.
3. Stop taking Genologix Biotin 500mcg if you get any side effects (see section 4).

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

If you take more Genologix Biotin 500mcg than you should

Biotin is not known to be harmful in overdose. Taking more than recommended may cause false results in laboratory tests.

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

If you forget to take Genologix Biotin 500mcg

If you forget a dose, take your next dose at the usual time the next day.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Genologix Biotin 500mcg

You can stop taking Genologix Biotin 500mcg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Biotin 500mcg can have side effects.

Not all side effects reported for Genologix Biotin 500mcg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Biotin 500mcg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Biotin 500mcg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Genologix Biotin 500mcg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- stomach upset or nausea (feeling sick),
- skin rash.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Biotin 500mcg.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

5. How to store Genologix Biotin 500mcg

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Protect from light and moisture.
- Keep the capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Biotin 500mcg if the pouch seal is broken or the capsules look damaged.

Return all unused medicine 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 Genologix Biotin 500mcg contains

The active substance is D-biotin (vitamin B7).

Active ingredient	Per capsule	Per daily dose (1 capsule)
D-Biotin (vitamin B7)	500 µg	500 µg

The other ingredients are microcrystalline cellulose, magnesium stearate and hypromellose (the vegan capsule shell).

Microcrystalline cellulose is a plant fibre used as a filler. It makes sure that every capsule contains the correct amount of the active ingredient. Magnesium stearate is a common ingredient in foods and medicines. A very small amount is used to help the powder flow smoothly through our production machines. These ingredients are not active ingredients. They are only used to help us make the capsules accurately and consistently.

What Genologix Biotin 500mcg looks like and contents of the pack

Clear, hard vegan (hypromellose) capsules filled with a white powder.

120 capsules (120 daily doses) packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

Access to the corresponding Professional Information

The Professional Information for Genologix Biotin 500mcg is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.