PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX NICOTINAMIDE 500mg hard capsules

Nicotinamide (niacinamide, vitamin B3) 500 mg per daily dose (2 capsules, each containing 250 mg)
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 on the product pages at https://genologix.co.za/product/genologix-nicotinamide-niacinamide-500mg-30-days-supply/ (30-day pack) and https://genologix.co.za/product/genologix-nicotinamide-niacinamide-500mg-bulk-120-days-supply/ (120-day pack).

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

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

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Nicotinamide 500mg 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 Nicotinamide 500mg is and what it is used for
2. What you need to know before you take Genologix Nicotinamide 500mg
3. How to take Genologix Nicotinamide 500mg
4. Possible side effects
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6. Contents of the pack and other information

1. What Genologix Nicotinamide 500mg is and what it is used for

Genologix Nicotinamide 500mg is a health supplement. It contains nicotinamide (also called niacinamide), a form of vitamin B3.

Unlike nicotinic acid (niacin), nicotinamide does not usually cause flushing (redness and warmth of the skin).

Genologix Nicotinamide 500mg:

- helps to metabolise carbohydrates, fats and proteins;
- contributes to normal growth and development; and
- is a factor in the maintenance of good health.

2. What you need to know before you take Genologix Nicotinamide 500mg

Do not take Genologix Nicotinamide 500mg:

- if you are hypersensitive (allergic) to nicotinamide or any of the other ingredients of Genologix Nicotinamide 500mg (listed in section 6).

Warnings and precautions

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

- if you have liver disease;
- if you have diabetes, because high doses of nicotinamide may affect blood sugar control;
- if you have a stomach ulcer or gout; or
- if you take any of the medicines listed under "Other medicines and Genologix Nicotinamide 500mg".

Vitamin B3 (niacin, nicotinamide or NMN) from other supplements should be taken into account when taking Genologix Nicotinamide 500mg.

Children and adolescents

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

Other medicines and Genologix Nicotinamide 500mg

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

Nicotinamide may increase the blood levels of:

- carbamazepine or primidone (medicines used to treat epilepsy).

Talk to your doctor before you take it if you take medicine for diabetes.

Genologix Nicotinamide 500mg with food, drink and alcohol

Take Genologix Nicotinamide 500mg with food (see section 3). Drinking a lot of alcohol while taking it may increase the risk of liver side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, consult your health care provider before taking Genologix Nicotinamide 500mg. The dose is much higher than the amount needed during pregnancy.

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 Nicotinamide 500mg is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Nicotinamide 500mg 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 Nicotinamide 500mg affects you.

Genologix Nicotinamide 500mg contains

Genologix Nicotinamide 500mg contains no sugar and no sweeteners.

3. How to take Genologix Nicotinamide 500mg

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

Always take Genologix Nicotinamide 500mg 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 two (2) capsules once a day. This provides 500 mg of nicotinamide.

Do not take more than two (2) capsules in 24 hours.

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

How to take it:

1. Take the capsules with food.
2. Swallow the capsules whole with a glass of water.
3. Stop taking Genologix Nicotinamide 500mg 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 Nicotinamide 500mg than you should

If you take too many capsules, you may get nausea, stomach upset, diarrhoea or headache. Very high doses taken for a long time may affect the liver.

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 Nicotinamide 500mg

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 Nicotinamide 500mg

You can stop taking Genologix Nicotinamide 500mg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Nicotinamide 500mg can have side effects.

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

If any of the following happens, stop taking Genologix Nicotinamide 500mg 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 Nicotinamide 500mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- nausea (feeling sick) or stomach upset,
- diarrhoea,
- headache or dizziness,
- mild flushing or itching of the skin.

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 Nicotinamide 500mg.

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 Nicotinamide 500mg

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 Nicotinamide 500mg 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 Nicotinamide 500mg contains

The active substance is nicotinamide (niacinamide, vitamin B3).

Active ingredient	Per capsule	Per daily dose (2 capsules)
Nicotinamide (niacinamide, vitamin B3)	250 mg	500 mg

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 Nicotinamide 500mg looks like and contents of the pack

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

Genologix Nicotinamide 500mg is available in two pack sizes: 60 capsules (30 daily doses) and 240 capsules (120 daily doses). Both are 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 Nicotinamide 500mg 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.