

PROFESSIONAL INFORMATION
**D 34.12 Multiple substance formulation
 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

BIOGEN NMN (Vegetable capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each Vegetable Capsule Contains:

β- Nicotinamide mononucleotide (NMN) 500,00 mg
 (providing nicotinamide 181,79 mg)

Orafti® P95 (95 % Organic Inulin Powder) 70,00 mg

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable Capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN NMN (Nicotinamide mononucleotide), a precursor of nicotinamide adenine dinucleotide (NAD+), an essential enzyme involved in cellular health and energy production.

4.2 Posology and method of administration

Adults 18 years and older:

Take 1 (one) vegetable capsule daily with meals, or as recommended by your healthcare provider

4.3 Contraindications

- If you are allergic to any of the ingredients listed in 6.1.
- If you have a hypersensitivity to any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN NMN.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

- Consult a healthcare provider if symptoms persist or worsen.
- Nicotinamide and its derivatives might theoretically increase the risk of bleeding. Use with caution in patients with existing bleeding disorders.

Nutritional supplementation should not replace a balanced diet.

Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

Interactions may occur. If you suffer from any serious ailments or conditions, or if you are taking any prescribed medications, give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

• Anticoagulant / Antiplatelet medicine:

Concomitant use of Nicotinamide and its derivatives with anticoagulant or antiplatelet medicine can have additive effects, especially in patients with hemodialysis.

• Carbamazepine (Tegretol):

Nicotinamide and derivatives might increase the levels and adverse effects of carbamazepine.

• Primidone (Mysoline):

Nicotinamide and derivatives might increase the levels and adverse effects of primidone.

Interactions with Diseases / Impairments

Bleeding disorders: Nicotinamide and derivatives might theoretically increase the risk of bleeding – use with caution in patients with existing bleeding disorders.

Discontinue use at least 2 weeks prior to elective surgical procedures.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN NMN.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN NMN does not adversely affect their performance.

4.8 Undesirable effects

Orally, BIOGEN NMN is well-tolerated but it can have side effects. Not all side effects reported for BIOGEN NMN are included in this leaflet.

Most Common Adverse Effects:

Orally: Bloating, constipation, muscle pain, nausea, pruritus, sweating, and transient changes in stools.

Dermatologically (Frequency unknown): Mild cases of flushing, skin rash, pruritus, and excessive sweating. (Rare): Flushing and skin rash.

Gastrointestinal disorders (Frequency unknown): Mild cases of nausea, bloating, and transient changes in stools. (Rare): Abdominal discomfort, diarrhea, and dyspepsia.

Immune system disorders (Frequency unknown): Hypersensitivity reaction (such as rash). (Rare): Severe allergic reactions to inulin-containing foods have been reported.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BIOGEN NMN is important. It allows continued monitoring of the benefit/risk balance of BIOGEN NMN. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic and supportive

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties

Category and class:

D 34.12 Multiple substance formulation

Complementary Medicine: Health supplement.

Mechanism of Action:

Nicotinamide, via its major metabolite NAD+ (nicotinamide adenine dinucleotide), is involved in a wide range of biological processes, including the product of energy, the synthesis of fatty acids, cholesterol and steroids, signal transduction and the maintenance of the integrity of the genome.

Mechanism of Action:

Some research suggests that inulin decreases levels of some inflammatory markers, including C-reactive protein (CRP), tumor necrosis factor-alpha, and interleukin (IL)-6. The anti-inflammatory effects of inulin may be related to its prebiotic effects

5.2 Pharmacokinetic properties
NMN (Nicotinamide mononucleotide)

Absorption: Nicotinamide is a precursor in the biosynthetic pathway of nicotinamide adenine dinucleotide (NAD+). Absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

Metabolism: Nicotinamide is converted to niacinamide by intestinal bacteria.

Excretion: Nicotinamide has a half-life of 2.7 hours.

Inulin

Absorption: Inulin is not digested or absorbed. Instead it promotes the growth of specific types of bacteria in the large intestine. These bacteria produce short-chain fatty acids that are absorbed and metabolized.

5.3 Preclinical safety data (Adults)

Likely safe when used orally and appropriately.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Off-white vegetable capsule, silicon dioxide, magnesium dioxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Store in the original package in order to protect from moisture.

6.5 Nature and contents

175 ml PET Container and Biogen Embossed cap

Pack sizes: 30 Vegetable Capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen,
 23 Stag Rd,
 Glen Austin,
 South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF FIRST AUTHORISATION

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JOB: BPS_NMNN_30s	SIZE: 210mm x 220mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
COLOURS:	FINISHING:
<input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV <input type="checkbox"/> Dorrning <input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY	
Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	