

PROFESSIONAL INFORMATION

D34.12 MULTIPLE SUBSTANCE FORMULATION. COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE BIOGEN MAGNISOL SLEEP (POWDER)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 7 g powder (1 Measuring spoon) contains:

| | | *%NRV |
|------------------------------|-------------|---------|
| Magnesium Bisglycinate | 2 500,00 mg | 60 % |
| Inositol | 1 000,00 mg | 1 000 % |
| Vitamin C (as Ascorbic acid) | 1 000,00 mg | 1 000 % |

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

Contains sweetener: Sucralose 45 mg per 7 g (1 Measuring spoon).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM POWDER.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN MAGNISOL SLEEP helps support muscle function, maintain electrolyte balance, and support a healthy immune system while reducing oxidative stress.

4.2 Posology and method of administration

Posology

Adults 18 years and older:

Mix 7 g of powder (± 1 scoop) in 300 ml of water to be taken at bedtime, or as recommended by your healthcare provider. Use the included measuring spoon for accurate dosing. Shake container before use.

The safety and efficacy of BIOGEN MAGNISOL SLEEP in children and adolescents has not yet been established.

4.3 Contraindications

- If you have a hypersensitivity to any of the ingredients or the excipients listed in 6.1.
- Not recommended for use in children under the age of 18 years.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN MAGNISOL SLEEP

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant, or breastfeeding.
- Caution is advised in individuals with impaired renal function when using magnesium, as decreased renal function can lead to elevated serum magnesium levels, potentially resulting in toxicity.
- Caution is advised with high doses of magnesium, it may cause hypomotility of the bowel.
- Caution is advised for individuals with diabetes as inositol may affect blood sugar levels.
- Caution is advised as excessive vitamin C intake may lead to kidney stone formation and may increase iron absorption.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interactions with other medicines and other forms of interactions

Interactions with Medicines, Diseases / Impairments

Antibiotics: Magnesium can interfere with the absorption of certain antibiotics, such as tetracyclines and quinolones, potentially reducing their effectiveness. It's advisable to separate the dosing times of magnesium supplements and these antibiotics by at least two hours.

Calcium Channel Blockers: Magnesium may enhance the effects of calcium channel blockers, leading to an increased risk of adverse effects like hypotension. Monitoring blood pressure is recommended when these are used concomitantly.

Diuretics: Certain diuretics can either increase the excretion of magnesium, leading to deficiency, or decrease excretion, leading to elevated levels. Regular monitoring of magnesium levels is advised when taken with diuretics.

Other Supplements: Combining magnesium with other supplements, such as those containing potassium or calcium, may require monitoring to maintain electrolyte balance and prevent potential interactions.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3).

4.7 Effects on ability to drive and use machines

- 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 BIOGEN MAGNISOL SLEEP does not adversely affect their performance.

4.8 Undesirable effects

Orally, BIOGEN MAGNISOL SLEEP is well-tolerated.

Summary of adverse reactions

BIOGEN MAGNISOL SLEEP can have side effects.

Gastrointestinal disorders: *Common:* Nausea, vomiting, diarrhea, and abdominal pain.

Hypermagnesemia: *Rare:* Hypermagnesemia.

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

If any of the following happens, stop using BIOGEN MAGNISOL SLEEP and tell your doctor or pharmacist immediately, or go 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 BIOGEN MAGNISOL SLEEP. You may need urgent medical attention or hospitalisation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit / risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: D34.12 Multiple Substance Formulation. Complementary Medicine

Mechanism of action:

Magnesium: contributes to energy metabolism, nervous system function, electrolyte balance, muscle function, and the maintenance of bones and teeth. It plays a role in carbohydrate, fat, and protein metabolism, tissue formation, psychological function, and cell division. It also helps reduce tiredness and fatigue while supporting overall health.

Inositol: supports normal cell signalling, neurotransmitter function, and lipid metabolism. It contributes to maintaining healthy brain function, psychological well-being, and normal ovarian function. Additionally, it plays a role in insulin signalling and hormone balance. Inositol is commonly used as part of multi-nutrient formulations for cognitive support, metabolic health, and reproductive function.

Vitamin C: supports iron absorption, fat and protein metabolism, and immune function. It aids in collagen formation for bones, cartilage, teeth, gums, and blood vessels, contributing to wound healing and connective tissue formation. As an antioxidant, it helps protect cells from free radical damage and supports overall health.

5.2 Pharmacokinetic properties

Magnesium

Absorption: Magnesium improves absorption compared to inorganic salts (e.g., magnesium oxide). Absorbed primarily in the small intestine.

Distribution: Distributed to tissues, with high affinity for bones, muscles, and the nervous system.

Metabolism: Magnesium itself is not metabolized but utilized directly in enzymatic reactions.

Excretion: Primarily excreted via the kidneys in urine.

Inositol

Absorption: Rapidly absorbed in the small intestine.

Distribution: Found in the brain, liver, and muscles.

Metabolism: Converted into inositol phosphates and phosphatidylinositol.

Excretion: Eliminated via the kidneys in urine.

Vitamin C

Absorption: Actively absorbed in the small intestine; efficiency decreases at high doses (>200 mg).

Distribution: High in the adrenal glands, liver, and immune cells.

Metabolism: Partially metabolized in the liver; functions as an antioxidant.

Excretion: Excess excreted in urine; high doses increase oxalate excretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid, Malic Acid, Flavour, Colour and Silicon Dioxide.

6.2 Incompatibilities

No compatibility studies have been performed; BIOGEN MAGNISOL SLEEP must not be mixed with other medications.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Protect from moisture and store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label.

Return all unused BIOGEN MAGNISOL SLEEP to your pharmacist.

Do not dispose of unused BIOGEN MAGNISOL SLEEP in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of the container

White to off-white powder, packed in a plastic container with a tamper evident seal and a plastic screw cap. Pack sizes of 210 g.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: info@biogen.co.za

Website: www.biogen.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.