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BIOGEN
FOR THE RESULTS YOU WANT

NEURO HEALTH

PROFESSIONAL INFORMATION

D 33.7 Combination Product. Complementary medicine.

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 NEURO HEALTH vegetarian capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetarian capsule contains:		%NRV*
Rhodiola rosea L. (Arctic root)	150,00 mg	
[Root, extract standardised to 3 % Salidrosides]		
Inositol	150,00 mg	
Magnesium (as Magnesium oxide)	60,30 mg	14 %
Pantothenic acid (Vitamin B_5)	10,00 mg	200 %
(from calcium D-pantothenate)		
Zinc (as zinc gluconate)	7,17 mg	65 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)
Sugar Free
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Vegetarian Capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
BIOGEN NEURO HEALTH, with Rhodiola extract that may relieve stress-related fatigue, and support mental focus and performance. Combined with inositol, Magnesium, Vitamin B_5 and Zinc to support healthy energy metabolism and nervous system function.

4.2 Posology and method of administration
Adults: Take 1 (one) capsule twice daily before meals, or as recommended by your healthcare provider.

The safety and efficacy of BIOGEN NEURO HEALTH in children younger than 18 years has not yet been established. Not allowed in children under 18 years.

4.3 Contraindications
- If you have a hypersensitivity to Rhodiola, Inositol, Magnesium, Vitamin B_5 and Zinc or any of the excipients listed in 6.1.
- Do not use this product if you have bipolar disorder or bipolar spectrum disorder.
- Not recommended during pregnancy and lactation.

4.4 Special warnings and precautions for use
Special care should be taken with BIOGEN NEURO HEALTH.
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 if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Consult a healthcare provider prior to use if you are taking antidepressant medication, hormone replacement therapy (HRT) or birth control medication (HC).
- Stop use if you experience irritability or insomnia.

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 with Medicines
- Concomitant use of Rhodiola with antidiabetic drugs might increase the risk of hypoglycemia, Rhodiola extract can decrease blood glucose due to alpha-glucosidase activity.
- Rhodiola extract inhibits angiotensin-converting enzyme (ACE) and might lower blood pressure, taking Rhodiola with antihypertensive drugs might increase the risk of hypotension.
- Rhodiola inhibits CYP1A2 and CYP2C9, and might increase levels of drug metabolized by CYP1A2 and CYP2C9.
- Rhodiola has immunostimulatory effects, and might interfere with immunosuppressive therapy, and might increase the levels and adverse effects of losartan.
- Rhodiola inhibits P-glycoprotein, and might increase levels of P-glycoprotein substrates.
- Inositol can lower blood glucose levels, taking inositol with antidiabetes drugs might increase the risk of hypoglycemia.
- Magnesium can bind with certain medications, preventing their full absorption. If you are taking a tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), separate the time of the dose from the time of the magnesium supplement dose by at least 2 to 3 hours.
- If you are taking a bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), or a quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), ask your doctor or pharmacist about how long you should wait between doses and for help finding a dosing schedule that will work with all your medications.
- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Zinc and Amiloride can modestly reduce zinc excretion and increase zinc levels, decrease cephalexin levels by chelating with cephalexin in the gut and preventing its absorption.
- Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.
- Zinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5-1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.
- Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.

Interactions with Diseases/Impairments
- Rhodiola might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Rhodiola might have immunostimulatory effects.
- Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement.

Interactions with Foods
- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing /suggesting BIOGEN NEURO HEALTH.

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 NEURO HEALTH does not adversely affect their performance.

4.8 Undesirable effects
Orally, Rhodiola, Inositol, Magnesium, Vitamin B_5 and Zinc is well-tolerated.

Summary of adverse reactions
Gastrointestinal disorders:
Frequent: Abdominal cramps, diarrhea, metallic taste, nausea and vomiting.
Nervous system disorders:
Frequent: Drowsiness, dizziness, insomnia, vivid dreams and headaches.
Other:
Frequency unknown: Rhodiola may cause increased or decreased production of saliva.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care 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
Mechanism of action*:*

Rhodiola, Rhodiola contains over 30 compounds including phenlyethanoids, phenylpropanoids, flavonoids, cyanoglycosides, monoterpenes, and triterpenes. The phenylpropanoid glycoside called salidroside, rhodioloside, or rhodosine is thought to be responsible for many of the stimulant or "adaptogenic" effects of rhodiola.

Inositol, a constituent of the intracellular phosphatidyl inositol second messenger system, which is linked to several neurotransmitters including alpha 1 noradrenergic, serotonin, dopamine, norepinephrine, glutamate and cholinergic receptors. Inositol may play a role in the interactions between G protein-coupled receptors and their ligands particularly in the serotonergic pathway.

Magnesium, intake increased levels of melatonin and reduced levels of cortisol, which might contribute to improved sleep. Additionally, low magnesium levels have been linked to poor sleep quality and also to electroencephalogram (EEG) abnormalities during slow wave sleep.

Zinc, in neurological conditions might be both protective and causative. Zinc might contribute to aggregation of amyloid beta peptide, but protect against subsequent neurotoxicity as an antioxidant. Zinc levels and zinc intake appear to be reduced in some people with depression. Zinc is believed to play a role in the hippocampus in communication between neurons. Zinc is also believed to potentiate the activity of some antidepressants. Taking zinc along with antidepressant treatment improves depression scores in patients diagnosed with major depression better than antidepressant alone.

Vitamin B_5, required for intermediary metabolism of carbohydrates, proteins, and lipids. Dexpanthenol is converted in the body to pantothenic acid.

5.2 Pharmacokinetic properties
Rhodiola, Rhodiola root extract appears to inhibit the activity of monoamine oxidase B (MAOB) in vitro, which suggests that it may have protective effects against MAOB-related neurodegenerative diseases.

Inositol, Endogenous inositol is an essential component of cell membrane phospholipids. It has weak lipotropic activity, and can move fat out of liver and intestine cells. Inositol has a variety of stereoisomers, including myo-inositol and D-chiro-inositol. Myo-inositol is the most abundant form in the central nervous system (CNS). Biological function varies among the isomers. Myo-inositol is a source of second messengers such as diacylglycerol.

Magnesium, has been theorized to regulate sleep by reducing inflammation, oxidative stress and by activating N-methyl-D-aspartate and gamma-aminobutyric acid (GABA) receptors.

Zinc, is a biologically essential trace element and is the second most abundant trace element in the body. The total body content is about 2 grams. It is a cofactor in many biological processes including DNA, RNA, and protein synthesis. About 30% of cellular zinc is found within the nucleus.

Vitamin B_5, required in the acetylation reactions in gluconeogenesis; in the release of energy from carbohydrates; in the synthesis and degradation of fatty acids; and in the synthesis of sterols, steroid hormones, porphyrins, acetylcholine, and other compounds.

Rhodiola:
Absorption: The bioavailability of salidroside, a constituent of rhodiola, was 32.1 %.
Distribution: No clinical data are available
Metabolism: No clinical data are available
Excretion: When administered at a dose of 12 mg/kg, the mean residence time of salidroside was 41.7 minutes when given orally and 17.9 minutes.

Inositol:
Absorption: Orally, inositol is transported across the intestinal mucosa and absorbed almost completely. The increase in serum concentration of inositol following intravenous administration appears to persist for 24-36 hours.
Metabolism: Inositol is metabolized by myo-inositol oxidase, which is located at the renal cortex. However, metabolism is complex and appears to change in utero, at birth, and is affected by enteral intake and endogenous controls.
Excretion: Because myo-inositol oxidase, the enzyme that metabolizes inositol, is less active in newborns, urinary excretion of inositol is higher in premature and term infants compared to infants that are a few weeks old.

Magnesium:
Absorption: requires both parathyroid hormone and vitamin D for absorption. It is absorbed throughout the gastrointestinal tract and about one third of dietary magnesium is absorbed. The efficiency of absorption depends on magnesium stores in the body. Average absorption of supplements is 38 %, but varies from 65 % in people with low magnesium stores to 11 % in those with high magnesium stores. Magnesium plasma concentrations peak at 4 hours after a dose.
Distribution: The body contains about 25 grams of magnesium, which is divided in roughly equal portions between the skeleton and soft tissue. About a third of skeletal magnesium is at the surface of the bone and acts as a reservoir to maintain extracellular magnesium concentrations.
Excretion: Magnesium excretion is primarily via the kidneys and averages only 3 % to 5 % of the filtered load. Excretion ranges from 10 to 5000 mg over a 24-hour period.

Zinc:
Distribution: More than 85% of the total zinc in the body is in skeletal muscle and bone.
Metabolism: Zinc going rapidly to the liver, followed by two component exponential loss patterns, levels decreased from a maximum of 1.2% of that ingested 3 hours after intake to 0.7% by 24 hours.
Excretion: Most zinc is excreted in the feces, with a small amount eliminated in the urine. However, urinary zinc levels appear to increase in patients with type 2 diabetes and congestive heart failure.

Vitamin B_5:
Excretion: Pantothenic acid is excreted in the urine.

Distribution/ Metabolism/ Excretion:
No clinical data are available on the effects of BIOGEN NEURO HEALTH.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Magnesium stearate.

6.2 Incompatibilities
No compatibility studies has been performed, BIOGEN NEURO HEALTH must not be mixed with other medications.

6.3 Shelf Life
24 Months.

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

6.5 Nature and contents
175 ml white PET container with a Biogen cap.
Pack size: 60 capsules.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Biogen
Biogen, 23 Stag Rd,
Glen Austin, South Africa
info@biogen.co.za,
www.biogen.co.za
0860 347 243

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.

10. DATE OF REVISION OF THE TEXT
February 2023.

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