



PROFESSIONAL INFORMATION

Scheduling Status: **SO**

1. Proprietary Name

Sleep Support

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
Magnesium (as <i>S. cerevisiae</i>) Providing elemental Magnesium 32 mg	160 mg
Zinc (as Lynside® Forte ZN100K) Providing elemental Zinc 5 mg	50 mg
<i>Valeriana officinalis</i> (Valerian) [root, as 50 mg of a 4:1 extract providing 200 mg dried herb equivalent]	200 mg
<i>Withania somnifera</i> (Ashwagandha) [root, as 10 mg of a 15:1 extract providing 150 mg dried herb equivalent]	150 mg
<i>Passiflora incarnata</i> (Passionflower), leaf powder	100 mg
<i>Ocimum sanctum</i> (Holy basil) [herb, 10 mg of a 10:1 extract providing 100 mg dried herb equivalent]	100 mg
<i>Melissa officinalis</i> (Lemon balm), leaf powder	80 mg

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical Form

60 white size 0 capsules containing light brown coloured, free-flowing powder.

4. Clinical Information

4.1 Indications for Use

Indicated where a deficiency in the active ingredients may exist. May aid temporary relaxation and assist with a reduction of sleeplessness.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 2 capsules 20-30 minutes before bedtime.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.



4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Not recommended for individuals who are under the age of 18. Not recommended for individuals who are pregnant or breastfeeding. Do not exceed the recommended daily dose.

4.5 Interactions

S. cerevisiae: Major risk of interactions with MAOIs. Moderate risk of interactions with antidiabetic drugs and lithium.

Magnesium: Moderate risk of interactions with aminoglycoside antibiotics, antacids, bisphosphonates, calcium channel blockers, digoxin, ketamine, quinolone antibiotics, skeletal muscle relaxants, sulfonyleureas, and tetracycline antibiotics. Major risk of interactions with levodopa/carbidopa.

Zinc: Moderate risk of interactions cephalixin, cisplatin, integrase inhibitors, penicillamine, quinolone antibiotics, ritonavir, and tetracycline antibiotics.

Valerian: Moderate risk of interactions with alcohol, alprazolam, CNS depressants and glucuronidase drugs.

Ashwagandha: Moderate risk of interactions with antidiabetic drugs, antihypertensive drugs, benzodiazepines, CNS depressants, immunosuppressants and thyroid hormone.

Passionflower: Moderate risk of interactions with CNS depressant drugs.

Holy basil: Moderate risk of interactions with anticoagulant drugs, antidiabetic drugs and pentobarbital.

Lemon balm: Moderate risk of interactions with CNS depressant drugs and thyroid hormone.

4.6 Pregnancy and Lactation

Not recommended for individuals who are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machinery.

May cause drowsiness.

4.8 Side Effects

Side effects may include mild gastrointestinal disturbances, such as nausea, diarrhoea, constipation, indigestion, bloating, metallic taste in the mouth, and flatulence. High doses of valerian root extract may cause dizziness, or drowsiness.

5 Pharmacological Classification

Category D: 33.7 Combination Product.

Complementary Medicine.

6 Pharmacokinetic Properties

Magnesium:

Absorption: Vitamin D and parathyroid hormone is required for the absorption of magnesium. The absorption of magnesium takes place in the tract and one third of magnesium is absorbed. The percentage of absorption is linked to the magnesium stores in the body. The average absorption of magnesium may vary from 11% in people with high percentage magnesium stores to 65% in people with low magnesium stores. Fractional magnesium absorption decreases with increasing intake. Magnesium chloride, magnesium lactate, and magnesium aspartate appear to have the best bioavailability.

Distribution: Magnesium is divided equally between the skeletal frame and soft tissue, which equates to about 25 g. A third of skeletal magnesium is at the surface of the bone, this maintains the concentration of extracellular magnesium. The remaining two-thirds is bound to the bone and not available for use. Magnesium undergoes a filter-reabsorption process in the proximal tube. The filtered magnesium is reabsorbed in the Loop of Henle. Both magnesium and calcium are transported on the ascending limb at the basolateral surface and compete for the transportation. Calcium, plasma magnesium and parathyroid level alterations all contribute to the reabsorption of magnesium.

Excretion: Magnesium is excreted primarily through the kidneys.



Zinc:	77
Absorption: the bioavailability of zinc depends on the zinc status of the body. If a zinc deficiency exists absorption will increase. Absorption takes place mostly in the small intestine. Zinc oxide is best absorbed in an acidic environment, and zinc acetate has a much wider range of pH to function in.	78
Diet plays a big role in Zinc absorption. Diets high in phytate have a lower absorption rate than diets high in protein. Although some protein sources such as bovine serum albumin and soy protein, may reduce absorption.	79
Distribution: the skeletal muscle and bone contain more than 85% of the Zinc	80
Metabolism: Zinc given orally rapidly goes to the liver and concentration levels decrease within 3 hours after intake.	81
Excretion: Zinc is mostly excreted in the faeces, with a small amount excreted in the urine	82
Valerian:	83
Absorption: after intake of 600 mg of valerian the maximum valerenic acid serum concentration of 0.9 ng / ml- 2.3 ng/ml occurred within 1-2 hours	84
Elimination: the elimination half-life of 600 mg oral dose valerenic acid is about 1.1 hours.	85
7. Pharmaceutical Information	86
7.1 List of Excipients	87
Vegetarian capsules, milled rice flour.	88
7.2 Incompatibilities	89
None noted.	90
7.3 Shelf Life	91
24 months from date of manufacture.	92
7.4 Storage	93
Store in a cool dry place, between 15°C -25°C. Store in original container.	94
7.5 Presentation	95
60 white capsules packed in a 300 ml cylindrical white container with a lid and packaged in a single carton.	96
7.6 Disposal and handling of product	97
All unused medication should be disposed of in accordance with local regulatory authority.	98
8. Holder of certificate of registration	99
FoodGrown™©	100
371 Angus Crescent	101
Northlands Business Park	102
North Riding	103
Gauteng	104
South Africa	105
9. Registration Number	106
Still to be allocated	107
10. Date of first authorisation	108
Still to be allocated	109
11. Date of review	110
New	111
12. Reference: https://naturalmedicines.therapeuticresearch.com/	112
APPLICANT DETAILS:	113
FoodGrown™©	114
371 Angus Crescent	115



FOODGROWN™©
Version 1.0
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Northlands Business Park
North Riding
Gauteng
South Africa
+27(0)87 265 4789

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