

Easy Sleep 40winx® Vegetarian Capsules

PROFESSIONAL INFORMATION

Complementary Medicine – Discipline Specific Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

Easy Sleep 40winx® Hard Shell Vegetarian Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Easy Sleep 40winx® is comprised of 2 Components:

Component 1:

Each Light Blue Sleep Capsule contains:

Chamomile [Herb] derived from <i>Matricaria recutita</i>	50	mg
Passion Flower [Herb 4:1 Extract] derived from <i>Passiflora incarnata</i>	25	mg
Valerian Root [Root 4:1 Extract] derived from <i>Valeriana officinalis</i>	25	mg
Calcium derived from Calcium Carbonate 200 mg	80	mg
Magnesium derived from Magnesium Oxide 133 mg	80	mg
L-Arginine derived from L-Arginine Hydrochloride 12 mg	10	mg
L-Glutamine	10	mg
L-Ornithine derived from L-Ornithine Hydrochloride 13 mg	10	mg
Vitamin D3 derived from Cholecalciferol 2 mg	200	IU

All minerals are expressed in their elemental and non-elemental forms.

Hard Capsule Shell of Vegetarian Origin.

Sucrose, Lactose, Gluten, and Tartrazine Free.

For full list of excipients, see section 6.1.

Component 2:

Each White Multivitamin Capsule contains:

Vitamin A derived from Vitamin A Acetate Complex 3 mg	1 000	IU
Vitamin B1 derived from Thiamine Mononitrate 6 mg	5	mg
Vitamin B2 derived from Riboflavin 2 mg	2	mg
Vitamin B3 derived from Nicotinamide 15 mg	15	mg
Vitamin B5 derived from Calcium-d-Pantothenate 5 mg	5	mg
Vitamin B6 derived from Pyridoxal-5-Phosphate Monohydrate 5 mg	5	mg
Vitamin B12 derived from Methylcobalamin 5 µg	5	µg
Vitamin C derived from Ascorbic Acid 100 mg	100	mg
Vitamin E derived from dl- α -Tocopheryl Acetate 20 mg	10	IU
Biotin	100	µg
Folate derived from (6S)-5-Methyltetrahydrofolate 565 µg	500	µg
Inositol derived from Myo-Inositol 100 mg	100	mg
Iron derived from Ferrous Bisglycinate 120 mg	24	mg

All minerals are expressed in their elemental and non-elemental forms.

Hard Capsule Shell of Vegetarian Origin.

Sucrose, Lactose, Gluten, and Tartrazine Free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Easy Sleep 40winx® is a 2 Component product.

Component 1

Size 0 Hard Shell Vegetarian Capsules.

Each Vegecap has a Light Blue body and Light Blue cap filled with a Beige coloured powder.

Component 2

Size 0 Hard Shell Vegetarian Capsules.

Each Vegecap has a White body and White cap filled with a Beige coloured powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Easy Sleep 40winx® is a health supplement for adults intended to help improve sleep and relaxation at night and give you an energetic start to the day. Easy Sleep 40winx® may also be helpful for the relief of mild symptoms of mental stress.

4.2 Posology and method of administration

For oral use.

The usual dose of Easy Sleep 40winx® is One Light Blue Capsule at Night an hour before bedtime and then One White Multivitamin Capsule in the Morning. Easy Sleep 40winx® must be taken with a meal.

In cases of severe sleeplessness, two Light Blue Sleep Capsules may be taken at Night for the first 14 days.

Take 2 hours before or after taking other medications or natural health products.

4.3 Contraindications

Do not use if you have a hypersensitivity to any of the ingredients, including the excipients listed in section 6.1.

Easy Sleep 40winx® should not be used by persons suffering from:

- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification);
- Wilson's disease (the disorder may be exacerbated);
- Hepatic and biliary disease.

4.4 Special warnings and precautions for use

Consult your healthcare professional if:

- your symptoms worsen;
- your sleeplessness persists for more than 3 weeks;
- you are following a low protein diet;
- you are taking antidepressant medication.

Consumption with alcohol or other medications or natural health products with sedative properties is not recommended.

The indicated daily dose should not be exceeded.

Easy Sleep 40winx® should not be given to children below the age of 18 years (due to the Amino Acid, Passion Flower, and Valerian content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

Alcohol: excessive intake of alcohol induces Thiamine deficiency, may increase renal excretion of Magnesium and increases the turnover of Pyridoxine.

Bisphosphonates: Calcium may reduce absorption of etidronate.

Calcitonin: Vitamin D may work against the effect of calcitonin.

Digoxin: caution because hypercalcaemia may potentiate effects of digoxin, resulting in cardiac arrhythmias.

4-Quinolones: Magnesium may reduce absorption of 4-quinolones if not given 2 hours apart.

Iron: Calcium Carbonate may reduce the absorption of Iron.

Tamoxifen: Calcium supplements may increase the risk of hypercalcaemia (a rare side-effect of tamoxifen therapy).

Tetracyclines: Magnesium may reduce absorption of tetracyclines if not taken 2 hours apart.

Thiazide diuretics: may increase excretion of Magnesium.

Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with Vitamin D supplements.

4.6 Fertility, Pregnancy and Breastfeeding

Always check with your doctor or pharmacist before taking any medicines if you are pregnant, planning to have a baby or breastfeeding.

The ingredients as contained in the Easy Sleep 40winx® Light Blue Sleep Capsule is not recommended to take while pregnant or breastfeeding.

The ingredients as contained in the Easy Sleep 40winx® White Multivitamin Capsule is commonly used in pregnancy products.

4.7 Effects on ability to drive and use of machines

The Easy Sleep 40winx® Light Blue Sleep Capsule may cause drowsiness and have an effect on the ability to drive or the use of machinery.

The Easy Sleep 40winx® White Multivitamin Capsule does not have any effect on the ability to drive or the use of machinery.

4.8 Undesirable effects

Organ System	Less Frequent
Gastrointestinal discomfort	Nausea, diarrhoea, constipation, indigestion, bloating and flatulence

Reporting of suspected adverse reactions:

If you experience any adverse reactions not mentioned in this leaflet, report it to AnaStellar Brands (Pty) Ltd. via pharmacist@anastellar.co.za, (011) 792 4601 or https://anastellar.co.za.

4.9 Overdose

Treatment of overdose should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Biotin: Biotin functions as an integral part of the enzymes that transport carboxyl units and fix carbon dioxide. Biotin enzymes are important in carbohydrate and lipid metabolism, and are involved in gluconeogenesis, fatty acid synthesis, propionate metabolism and the catabolism of Amino Acids.

Calcium: Calcium plays a structural role in bones and teeth and is essential for cellular structure, blood clotting, muscle contraction, nerve transduction, enzyme activation, and hormone function.

Chamomile: Chamomile in the form of an aqueous extract has been frequently used as a mild sedative to calm nerves and reduce anxiety, to treat hysteria, nightmares, insomnia, and other sleep problems.

Folate: Folates are involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of deoxyribonucleic acid (DNA), glycine and methionine). They are also involved in Amino Acid conversions as well as the formation and utilisation of formate. Deficiencies leads to impaired cell division (effects most noticeable in rapidly generating tissues).

Inositol: Plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells, including inositol phosphates, phosphatidylinositol (PI), and phosphatidylinositol phosphate (PIP) lipids.

Iron: Iron is a component of haemoglobin, myoglobin and many enzymes that are involved in a variety of metabolic functions, including transport and storage of oxygen, the electron transport chain, DNA synthesis, and catecholamine metabolism.

L-Arginine: L-Arginine plays a role in the formation of important physiological factors, including nitric oxide (NO, a vasodilator), urea (an excretory product), creatine (required for the storage of high energy phosphates), all proteins (as part of the structures), and growth hormone release.

L-Glutamine: Like other Amino Acids, Glutamine is biochemically important as a constituent of proteins. Glutamine is also crucial in nitrogen metabolism. Ammonia (formed by nitrogen fixation) is assimilated into organic compounds by converting glutamic acid to Glutamine. The enzyme which accomplishes this is called glutamine synthetase. Glutamine can then be used as a nitrogen donor in the biosynthesis of many compounds, including other Amino Acids, purines, and pyrimidines.

L-Ornithine: A non-essential and non-protein Amino Acid, Ornithine is critical for the production of the body's proteins, enzymes, and muscle tissue. Ornithine plays a central role in the urea cycle and is important for the disposal of excess nitrogen (ammonia). Ornithine is the starting point for the synthesis of many polyamines such as putrescine and spermine.

Magnesium: Magnesium is an essential cofactor for enzymes requiring adenosine triphosphate (ATP) (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of ribonucleic acid (RNA) and replication of deoxyribonucleic acid (DNA); neuromuscular transmission; and Calcium metabolism.

Passion Flower: Passion Flower is a traditional medicinal medicine for the relief of mild symptoms of mental stress and to aid sleep.

Valerian Root: Valerian interacts with neurotransmitters such as GABA and produces a dose-dependent release of GABA. Valerian also inhibits the enzyme-induced breakdown of GABA in the brain, with concomitant sedation. Valerian's inherent GABA content could directly cause sedation, although concerns exist regarding bioavailability. The Valerian lignan hydroxypinoresinol has been found to bind to benzodiazepine receptors. The valepotriates may act as prodrugs through biotransformation into homobaldrinal by bacterial flora. Finally, Valerian's sedative effect acts more as a nervous system depressant than as a muscle relaxant.

Vitamin A: Vitamin A (in the form of retinal) is essential for normal function of the retina, particularly for visual adaptation to darkness. Other forms (retina, retinoic acid) are necessary to maintain the structural and functional integrity of epithelial tissue and immune system, cellular differentiation and proliferation and bone growth. Vitamin A may act as a cofactor in biochemical reactions.

Vitamin B1: Thiamine functions as a coenzyme in the oxidative decarboxylation of alpha ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Thiamine is also important in nerve transmission (independently of coenzyme function).

Vitamin B2: Riboflavin functions as a component of two flavin coenzymes – flavin mononucleic (FMN) and flavin adenine dinucleotide (FAD). It participates in oxidation-reduction reactions in numerous metabolic pathways and in energy production. Examples include the oxidation of glucose, certain Amino Acids and fatty acids; reactions with several intermediates of the Krebs cycle; conversion of Pyridoxine to its active coenzyme; and conversion of tryptophan to Niacin. Riboflavin has a role as an antioxidant. It may be involved in maintaining the integrity of erythrocytes.

Vitamin B3: As a vitamin, Niacin functions as a component of two enzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide diphosphate (NADP). The coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, Amino Acid, and purine metabolism.

Vitamin B5: Pantothenic Acid functions mainly as a component of Coenzyme A and acyl carrier protein. Coenzyme A has a central role as a cofactor for enzymes involved in the metabolism of lipids, carbohydrates and proteins; it is also required for the synthesis of cholesterol, steroid hormones, acetylcholine, and porphyrins. As a component acyl carrier protein, Pantothenic Acid is involved in various transfer reactions and in the assembly of acetate units into longer-chain fatty acids.

Vitamin B6: Vitamin B6 is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in more than 100 reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also present in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g., the conversion of tryptophan to Niacin); and haemoglobin and sphingosine formation.

Vitamin B12: Vitamin B12 is active in the recycling of folate coenzymes and the degradation of valine. It is also required for nerve myelination, cell replication, haematopoiesis and nucleoprotein synthesis.

Vitamin C: The functions of Vitamin C are based mainly on its properties as a reducing agent. It is required for the formation of Collagen and other organic constituents of the intercellular matrix in bone, teeth, and capillaries, as well as the optimal activity of several enzymes. Vitamin C also acts as an antioxidant (reacting directly with aqueous free radicals), which is important in the protection of cellular function and to enhance the intestinal absorption of non-haem Iron.

Vitamin D: Vitamin D is essential for promoting the absorption and utilisation of Calcium and Phosphorous and normal calcification of the skeleton. Along with parathyroid hormone (PTH) and calcitonin, it regulates serum Calcium concentration by altering serum Calcium and phosphate blood levels as needed, and mobilising Calcium from bone. It maintains neuromuscular function and various other cellular processes, including immune system and insulin production.

Vitamin E: Vitamin E is an antioxidant, protecting polyunsaturated fatty acids in membranes and other critical cellular structures from free radicals and products of oxidation. It works in conjunction with dietary Selenium (a cofactor for glutathione peroxidase), as well as with Vitamin C and other enzymes, including superoxide dismutase and catalase.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component 1:
Magnesium Stearate
Microcrystalline Cellulose

Component 2:
Magnesium Stearate
Microcrystalline Cellulose

6.2 Incompatibilities

None.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Component 1
10 x Size 0 Light Blue Hard Shell Vegetarian Capsules contained in 3 x PVC/PVDC/Aluminium blister strips.

Component 2
10 x Size 0 White Hard Shell Vegetarian Capsules contained in 3 x PVC/PVDC/Aluminium blister strips.

Packed product:
Pack size of 30 x Light Blue Hard Shell Vegetarian Capsules of component 1 and 30 x White Hard Shell Vegetarian Capsules of component 2.
6 x PVC/PVDC/Aluminium blister strips enclosed within a cardboard carton.
Unit Carton with 1 x Tamper Proof Seal on each side of the lid openings.

6.6 Special precautions for disposal

No special requirements.

7. Holder of Certificate of Registration

AnaStellar Brands (Pty) Ltd.
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Fontainebleau
2032
South Africa
+27 (0)11 792 4601

8. Registration number

To be assigned

9. Date of first authorisation

TBC

10. Date of revision of the text

January 2025

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