PACKAGE INSERT

SCHEDULING STATUS
To be assigned

PROPRIETARY NAME AND DOSAGE FORM
EASY SLEEP 40 WINX Capsules

COMPOSITION
EASY SLEEP 40 WINX is comprised of 2 Components:

Component 1:

Each Clear Evening Capsule contains:	
Calcium (derived from Calcium Carbonate)	80 mg
Chamomile (as Chamomile Powder)	50 mg
L-Arginine (derived from L-Arginine Hydrochloride)	10 mg
L-Glutamine (as L-Glutamine)	10 mg
L-Ornithine (as L-Ornithine)	10 mg
Magnesium (derived from Magnesium Oxide)	80 mg
Passion Flower (as Passion Flower 4:1 Extract)	25 mg
Valerian Root (as Valerian Root 4:1 Extract)	25 mg
Vitamin D3 (as Cholecalciferol)	200 IU

Excipients: hard-gel vegetable capsule, magnesium stearate (vegetable), maize starch, silicon dioxide

Component 2:

Each White Multi-Vitamin Capsule contains:	
Vitamin A (derived from Vitamin A Acetate	500 IU
Vitamin B1 (derived from Thiamine Hydrochloride)	5 mg
Vitamin B2 (as Riboflavin)	5 mg
Vitamin B3 (as Nicotinamide)	10 mg
Vitamin B5 (derived from Calcium-D-Pantothenate)	10 mg
Vitamin B6 (derived from Pyridoxine Hydrochloride)	10 mg
Vitamin B12 (derived from Cyanocobalamin)	10 µg
Vitamin C (as Ascorbic Acid)	150 mg
Vitamin E (as dl-α-Tocopherol)	10 IU
Biotin (as Biotin)	25 µg
Folic Acid (as Folic Acid)	500 µg
Iron (derived from Iron Amino Acid Chelate)	15 mg
Inositol (as Myo-Inositol)	25 mg

Excipients: hard-gel vegetable capsule, magnesium stearate (vegetable), maize starch, silicon dioxide

PHARMACOLOGICAL CLASSIFICATION
D: 32.2 (Other): Combination Product – Western Herbal Medicine

PHARMACOLOGICAL ACTION
Pharmacodynamics:

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

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 transmission, 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.

Folic acid: 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 some amino acid conversions and the formation and utilisation of formate. Deficiency leads to impaired cell division (effects most noticeable in rapidly regenerating 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-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.

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.

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.

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

Vitamin A: Vitamin A (in the form of retinal) is essential for normal function of the retina, particularly for visual adaption to darkness. Other forms (retinol, 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 mononucleotide (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 intermediaries 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 coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide diphosphate (NADP). These 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 of 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; and 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 phosphorus 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 the 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), and also with vitamin C and other enzymes, including superoxide dismutase and catalase.

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.

INDICATIONS
EASY SLEEP 40 WINX is indicated for the relief of mild symptoms of mental stress and to aid sleep. Easy Sleep 40 WINX is designed to improve sleep and relaxation at night and give you an energetic start to the day.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients, including excipients.
Not for use in children and adolescents below the age of 18 years.
EASY SLEEP 40 WINX should not be used by persons suffering from:
- conditions associated with hypercalcaemia and hypercalcuria, 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.

WARNINGS AND SPECIAL PRECAUTIONS
Take 2 hours before or after taking other medications.
Consult your healthcare professional if you are following a low protein diet.
Consult a Doctor if sleeplessness persists for more than 3 weeks, if symptoms persist or worsen.
Consumption with alcohol, other medications or natural health products with sedative properties is not recommended.

Ability to drive and operate machinery
The Evening Capsule of EASY SLEEP 40 WINX may impair your ability to drive and use machines.

INTERACTIONS
Bisphosphonates: calcium may reduce absorption of etidronate.
4-Quinolones: calcium and magnesium may reduce absorption of 4-quinolones.
Tamoxifen: calcium supplements may increase the risk of hypercalcaemia (a rare side-effect of tamoxifen therapy).
Tetracyclines: calcium and magnesium may reduce absorption of tetracyclines.
Iron: calcium carbonate or calcium phosphate may reduce absorption of iron.
Zinc: calcium may reduce absorption of zinc.
Calcitonin: effect of calcitonin may be antagonised by vitamin D.
Digoxin: caution because hypercalcaemia caused by vitamin D may potentiate effects of digoxin, resulting in cardiac arrhythmias.
Thiazide diuretics: vitamin D may increase risk of hypercalcaemia.
Vitamin D analogues (alfacalcidol, calcitriol, dihydrotachysterol): increased risk of toxicity with vitamin D supplements.

PREGNANCY AND LACTATION
Safety during pregnancy and lactation has not been established.
The use of EASY SLEEP 40 WINX during pregnancy and lactation is not recommended.

DOSAGE AND DIRECTIONS FOR USE
For oral use.
Evening: Take one Clear Evening Capsule at night, about an hour before bedtime.
Morning: Take one White Multi-Vitamin Capsule with breakfast.
Take 2 hours before or after taking other medications.

SIDE EFFECTS
May cause mild gastrointestinal disturbances e.g. nausea, diarrhoea, constipation, indigestion, bloating and flatulence.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Vitamin D could (in exceptional circumstances) cause toxicity; the margin of safety is very narrow. There is a wide variation in tolerance to vitamin D.
Excessive intake leads to hypercalcaemia and its associated effects. These include apathy, anorexia, constipation, diarrhoea, dry mouth, fatigue, headache, nausea and vomiting, thirst and weakness. Later symptoms are often associated with calcification of soft tissues and include bone pain, cardiac arrhythmias, hypertension, renal damage (increased urinary frequency, decreased urinary concentrating ability; nocturia, proteinuria), psychosis (rare) and weight loss.
If an overdose is suspected, the medicine should be stopped immediately.

IDENTIFICATION
Component 1: Clear Capsule filled with a beige coloured powder.
Component 2: White Capsule filled with a beige coloured powder.

PRESENTATION
A cardboard carton containing blister strips of 30 Clear Evening Capsules and 30 White Multi-Vitamin Capsules.

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

REGISTRATION NUMBER
To be assigned

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
AnaStellar Brands (Pty) Ltd
Boskruin Business Park,
Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169,
Gauteng, Republic of South Africa
+27 (0)11 792 4601

DATE OF PUBLICATION OF THE PACKAGE INSERT
July 2016

This medicine has not been evaluated by the Medicines Control Council.
This medicine is not intended to diagnose, treat, cure or prevent any disease.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
To be assigned

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
EASY SLEEP 40 WINX Capsules

Read all of this leaflet carefully before you start taking EASY SLEEP 40 WINX

EASY SLEEP 40 WINX is available without a doctor's prescription, for you to treat a mild condition. Nevertheless you still need to use EASY SLEEP 40 WINX carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share EASY SLEEP 40 WINX with any other person
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT EASY SLEEP 40 WINX CONTAINS
EASY SLEEP 40 WINX is comprised of 2 Components:

Component 1:

Each Clear Evening Capsule contains:	
Calcium (derived from Calcium Carbonate)	80 mg
Chamomile (as Chamomile Powder)	50 mg
L-Arginine (derived from L-Arginine Hydrochloride)	10 mg
L-Glutamine (as L-Glutamine)	10 mg
L-Ornithine (as L-Ornithine)	10 mg
Magnesium (derived from Magnesium Oxide)	80 mg
Passion Flower (as Passion Flower 4:1 Extract)	25 mg
Valerian Root (as Valerian Root 4:1 Extract)	25 mg
Vitamin D3 (as Cholecalciferol)	200 IU

The other ingredients are hard-gel vegetable capsule, magnesium stearate (vegetable), maize starch and silicon dioxide.

Component 2:

Each White Multi-Vitamin Capsule contains:	
Vitamin A (derived from Vitamin A Acetate	500 IU
Vitamin B1 (derived from Thiamine Hydrochloride)	5 mg
Vitamin B2 (as Riboflavin)	5 mg
Vitamin B3 (as Nicotinamide)	10 mg
Vitamin B5 (derived from Calcium-D-Pantothenate)	10 mg
Vitamin B6 (derived from Pyridoxine Hydrochloride)	10 mg
Vitamin B12 (derived from Cyanocobalamin)	10 µg
Vitamin C (as Ascorbic Acid)	150 mg
Vitamin E (as dl-α-Tocopherol)	10 IU
Biotin (as Biotin)	25 µg
Folic Acid (as Folic Acid)	500 µg
Iron (derived from Iron Amino Acid Chelate)	15 mg
Inositol (as Myo-Inositol)	25 mg

The other ingredients are hard-gel vegetable capsule, magnesium stearate (vegetable), maize starch and silicon dioxide.

WHAT EASY SLEEP 40 WINX IS USED FOR
EASY SLEEP 40 WINX is indicated for the relief of mild symptoms of mental stress and to aid sleep. Easy Sleep 40 WINX is designed to improve sleep and relaxation at night and give you an energetic start to the day.

BEFORE YOU TAKE EASY SLEEP 40 WINX
Do not take EASY SLEEP 40 WINX if:
- Hypersensitive (allergic) to any of the ingredients of EASY SLEEP 40 WINX.
- You are younger than 18 years old.
- You suffer from chronic kidney disease or if you have high levels of calcium in either your blood or urine.
- You suffer from renal osteodystrophy with hyperphosphataemia (a bone disease caused by incorrect functioning of the kidneys).

Take special care with EASY SLEEP 40 WINX:
Take EASY SLEEP 40 WINX 2 hours before or after taking any medication.
Consult your healthcare professional if you are following a low protein diet.
Consult a Doctor if sleeplessness persists for more than 3 weeks, if symptoms persist or worsen.
Consumption with alcohol, other medications or natural health products with sedative properties is not recommended.

Taking EASY SLEEP 40 WINX with food and drink:
EASY SLEEP 40 WINX should be taken with food.

Pregnancy and breastfeeding:
It is not recommended to take EASY SLEEP 40 WINX while pregnant or breastfeeding.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
The evening capsules of EASY SLEEP 40 WINX may make you feel drowsy.

Taking other medicines with EASY SLEEP 40 WINX:
Always tell your healthcare professional if you are taking any other medicine.
This includes complementary or traditional medicines.

Bisphosphonates (used in the treatment of osteoporosis): calcium may reduce absorption of etidronate.

4-Quinolones (a group of antibiotics): calcium and magnesium may reduce absorption of 4-quinolones.

Tamoxifen (used in the prevention and treatment of breast cancer): calcium supplements may increase the risk of hypercalcaemia (high levels of calcium in the blood).

Tetracyclines (a type of antibiotic): calcium and magnesium may reduce absorption of tetracyclines.

Iron: calcium carbonate or calcium phosphate may reduce absorption of iron.

Zinc: calcium may reduce absorption of zinc.

Calcitonin (a hormone): vitamin D may work against the effect of calcitonin.

Digoxin (a medicine used to treat heart failure): high calcium levels in the blood caused by vitamin D may increase the effects of digoxin, resulting in cardiac arrhythmias (abnormal heart rhythm).

Thiazide diuretics (a medicine used to treat high blood pressure and water retention/swelling): vitamin D may increase the risk of hypercalcaemia (high levels of calcium in the blood).

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

HOW TO TAKE EASY SLEEP 40 WINX
Do not share medicines with any other person.
You should check with your doctor or pharmacist if you are unsure on how to use EASY SLEEP 40 WINX.

The usual dose is one clear evening capsule at night about an hour before bedtime and then one white multi-vitamin capsule in the morning with breakfast.
Take 2 hours before or after taking other medications.

If you take more EASY SLEEP 40 WINX than you should:
In the event of an overdosage, consult your doctor or pharmacist.
If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of EASY SLEEP 40 WINX:
Do not take a double dose to make up for a forgotten individual dose.

POSSIBLE SIDE-EFFECTS
EASY SLEEP 40 WINX can have side effects.
Not all side effects reported for EASY SLEEP 40 WINX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
You may (in exceptional cases) experience nausea, diarrhoea, constipation, indigestion, bloating and flatulence while taking EASY SLEEP 40 WINX.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF EASY SLEEP 40 WINX
Store all medicines out of reach of children.
Store at or below 25 °C.
Protect from light and moisture.
Keep the blister strips in the outer carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF EASY SLEEP 40 WINX
A cardboard carton containing blister strips of 30 Clear Evening Capsules and 30 White Multi-Vitamin Capsules.

IDENTIFICATION OF EASY SLEEP 40 WINX
Component 1: Clear Capsule filled with a beige coloured powder.
Component 2: White Capsule filled with a beige coloured powder.

REGISTRATION NUMBER:
To be assigned

NAME AND ADDRESS OF REGISTRATION HOLDER
AnaStellar Brands (Pty) Ltd
Boskruin Business Park,
Unit 15, North Wing, Ground Floor,
Bosbok Road, Randpark Ridge, 2169,
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July 2016

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VOUBILJET

SKEDULERINGSTATUS
Moet toegewys word

EIENDOMSNAAM EN DOSERINGSVORM
EASY SLEEP 40 WINX Kapsules

SAMESTELLING
EASY SLEEP 40 WINX bestaan uit 2 Komponente:

Komponent 1:

Elke Deurskynende Aand-kapsule bevat:	
Kalsium (verkry van Kalsiumkarbonaat)	80 mg
Kamille (as Kamillepoeier)	50 mg
L-Arginien (verkry van L-Arginienhidrochloried)	10 mg
L-Glutamien (as L-Glutamien)	10 mg
L-Ornitien (as L-Ornitien)	10 mg
Magnesium (verkry van Magnesiumoksied)	80 mg
Passieblom (as Passieblom 4:1 Ekstrak)	25 mg
Valeriaanwortel (as Valeriaanwortel 4:1 Ekstrak)	25 mg
Vitamien D3 (as Cholekalsiferol)	200 IE

Bindmiddels: harde-jel plant-kapsule, magnesiumstearaat (plant), mieliestysel en silikondioksied.

Komponent 2:

Elke Wit Multivitamien Kapsule bevat:	
Vitamien A (verkry van Vitamien A Asetaat)	500 IE
Vitamien B1 (verkry van Tiamienhidrochloried)	5 mg
Vitamien B2 (as Riboflavien)	5 mg
Vitamien B3 (as Nikotienamied)	10 mg
Vitamien B5 (verkry van Kalsium-D-Pantotenaat)	10 mg
Vitamien B6 (verkry van Piridoksienhidrochloried)	10 mg
Vitamien B12 (verkry van Sianokobalamien)	10 µg
Vitamien C (as Askorbiensuur)	150 mg
Vitamien E (as dl-α-Tokoferol)	10 IE
Biotien (as Biotien)	25 µg
Foliensuur (as Foliensuur)	500 µg
Yster (verkry van Ysteraminosuurchelaat)	15 mg
Inositol (as Mio-Inositol)	25 mg

Bindmiddels: harde-jel plant-kapsule, magnesiumstearaat (plant), mieliestysel, silikondioksied

FARMAKOLOGIESE KLASSIFIKASIE
D: 32.2 (Ander): Gesondheidsaanvulling

FARMAKOLOGIESE WERKING
Farmakodinamika:

L-Arginien: L-Arginien speel 'n rol in die vorming van belangrike fisiologiese faktore, insluitend stikstofmonoksied (NO, 'n vasodilator), ureum ('n uitskeidingsproduk), kreatien (nodig vir berging van hoë-energie fosfate), alle proteïene (as 'n deel van die strukture), en groeihormoonvrystelling.

Biotien: Biotien funksioneer as 'n integrale deel van die ensieme wat karboksieleenhede vervoer en koolstofdioksied bind. Biotienensieme is belangrik in koolhidraat- en lipiedmetabolisme, en is betrokke by glukoneogenese, vetsuursintese, propionaatmetabolisme en die katabolisme van aminosure.

Kalsium: Kalsium speel 'n strukturele rol in bene en tande en is noodsaaklik vir sellulêre strukture, bloedstolling, spiersametrekking, senuwee-oordrag, ensiemaktivering en hormoonfunksie.

Kamille: Kamille in die vorm van 'n waterige ekstrak is dikwels as 'n ligte kalmeermiddel gebruik om senuwees te kalmeer en angs te verminder, histerie, nagmerries, slaaploosheid en ander slaapprobleme te behandel.

Foliensuur: Foliensuur is by 'n aantal enkelkoolstof-oordrareaksies betrokke, veral in die sintese van puriene en pirimidiene (en gevolglik die sintese van deoksiribonukleïensuur (DNA)), glisien en metionien. Hulle is ook by sommige aminosuuromsettings en die vorming en benutting van formiaat betrokke. 'n Tekort lei tot belemmerde selverdeling (die uitwerkings is mees merkbaar by weefsel wat vinnig regenereer).

Inositol: Inositol speel 'n belangrike rol as die strukturele basis vir 'n aantal sekondêre boodskappers in eukariotiese selle, insluitend inositolfosfate, fosfatidielinositol (PI) en fosfatidielinositolfosfaat (PIP) lipiede.

Yster: Yster is 'n komponent van hemoglobien, mioglobien en talle ensieme wat by 'n verskeidenheid metaboliese funksies betrokke is, insluitend vervoer en berging van suurstof, die elektronvervoerketting, deoksiribonukleïensuur-(DNA) sintese en katesjolamienmetabolisme.

L-Glutamien: Soos ander aminosure is glutamien biochemies belangrik as 'n bestanddeel van proteïene. Glutamien is ook deurslaggewend by stikstofmetabolisme. Ammoniak (gevorm deur stikstofbinding) word in organiese verbindings geassimileer deur glutamiensuur in glutamien om te sit. Die ensiem wat dit teweegbring, word glutamiensintetase genoem. Glutamien kan dan as 'n stikstofskenker gebruik word in die biosintese van talle verbindings, insluitend ander aminosure, puriene, en pirimidiene.

Magnesium: Magnesium is 'n essensiële kofaktor vir ensieme wat adenosientrifosfaat (ATP) nodig het (hulle is betrokke by glikolise, vetsuuroksidasie en aminosuurmetabolisme). Dit is ook nodig vir die sintese van ribonukleïensuur (RNA) en replikasie van deoksiribonukleïensuur (DNA); neuromuskulêre oordrag; en kalsiummetabolisme.

L-Ornitien: Ornitien is 'n nie-essensiële en nie-proteïen aminosuur en is van kritieke belang vir die produksie van die liggaam se proteïene, ensieme en spierweefsel. Ornitien speel 'n sentrale rol in die ureumsiklus en is belangrik vir die opruiming van 'n oormaat stikstof (ammoniak). Ornitien is die beginpunt vir die sintese van talle poliamiene soos putressien en spermien.

Passieblom: Passieblom is 'n tradisionele medisinale middel vir die verligting van ligte simptome van geestesspanning en om slaap te bevorder.

Vitamien A: Vitamien A (in die vorm van retinaal) is noodsaaklik vir normale funksie van die retina, veral vir visuele aanpassing by donkerte. Ander vorms (retinol, retinoësuur) is nodig om die strukturele en funksionele integriteit van epiteelweefsel en die immuunstelsel, sellulêre differensiasie en proliferasie en beengroei in stand te hou. Vitamien A mag as 'n kofaktor in biochemiese reaksies optree.

Vitamien B1: Tiamien funksioneer as 'n koënsiem in die oksidatiewe dekarboksilasie van alfa-ketosure (betrokke by energieproduksie) en in die transketolasereaksie van die pentosefosfaatroete (betrokke by karbonaatmetabolisme). Tiamien is ook belangrik by senuweeoordrag (onafhanklik van koënsiemfunksie).

Vitamien B2: Riboflavien funksioneer as 'n komponent van twee flavienkoënsieme – flavienmonokleotied (FMN) en flavienadeniendinukleotied (FAD). Dit neem deel aan oksidasie-reduksiereaksies in talle metaboliese roetes en in energieproduksie. Voorbeelde sluit in die oksidasie van glukose, sekere aminosure en vetsure; reaksies met etlike tussengangers van die Krebs-siklus; omsetting van piridoksien tot sy aktiewe koënsiem; en omsetting van triptofaan in niasien. Ribovlafien het 'n rol as 'n antioksidant. Dit mag betrokke wees by die instandhouding van die integriteit van eritrosiete.

Vitamien B3: As 'n vitamien funksioneer niasien as 'n komponent van twee koënsieme, nikotienamiedadeniendinukleotied (NAD) en nikotienamiedadeniendinukleotieddifosfaat (NADP). Hierdie koënsieme neem aan talle metaboliese prosesse deel, insluitend glikolise, weefselrespirasie, lipied-, aminosuur- en purienmetabolisme.

Vitamien B5: Pantoteensuur funksioneer hoofsaaklik as 'n komponent van koënsiem A en asieldraerproteïen. Koënsiem A het 'n sentrale rol as 'n kofaktor vir ensieme wat by die metabolisme van lipiede, koolhidrate en proteïene betrokke is; dit is ook nodig vir die sintese van cholesterol, steroïedhormone, asetielcholien en porfiriene. As 'n komponent van asieldraerproteïen is pantoteensuur by verskeie oordrareaksies en by die samestelling van asetaateenhede in langer-ketting vetsure betrokke.

Vitamien B6: Vitamien B6 word in eritrosiete tot piridoksaalfosfaat en, in 'n mindere mate, piridoksamienfosfaat omgesit. Dit tree as 'n kofaktor op vir ensieme wat by meer as 100 reaksies betrokke is wat proteïen, lipied- en koolhidraatmetabolisme beïnvloed. Paradoksaalfosfaat is ook teenwoordig in die sintese van etlike senuoordragstowwe; die metabolisme van 'n aantal vitamiene (bv. die omsetting van triptofaan in niasien); en hemoglobien- en sfingosienvorming.

Vitamien B12: Vitamien B12 is aktief in die herbenutting van folaatkoënsieme en die afbreking van valien. Dit is ook nodig vir senuweemiëlinering, selreplikasie, hematopoïese en nukleoproteïensintese.

Vitamien C: Die funksies van vitamien C is hoofsaaklik op sy eienskappe as 'n reduseermiddel gegrond. Dit is nodig vir die vorming van kollageen en ander organiese bestanddele van die interssellulêre matrys in bene, tande en haarvate; en die optimale werking van etlike ensieme. Vitamien C werk ook as 'n antioksidant (reageer direk met waterige vry radikale), wat belangrik is in die beskerming van sellulêre funksie en om die intestinale opname van nieheemyster te bevorder.

Vitamien D: Vitamien D is noodsaaklik om die opname en benutting van kalsium en fosfor en normale kalsifisering van die skelet te bevorder. Saam met paratiroïedhormoon (PTH) en kalsitonien reguleer dit serumkalsiumkonsentrasie deur serumkalsium- en fosfaat-bloedvlakke te wysig soos nodig, en kalsium uit been te mobiliseer. Dit hou neuromuskulêre funksie en verskeie ander sellulêre prosesse in stand, insluitend die immuunstelsel en insulienproduksie.

Vitamien E: Vitamien E is 'n antioksidant wat poli-onversadigde vetsure in membrane en ander kritieke sellulêre strukture teen vry radikale en produkte van oksidasie beskerm. Dit werk tesame met dieetseleen ('n kofaktor vir glutatioonperoksidase) en ook met vitamien C en ander ensieme, insluitend superoksieddismutase en katalase.

Valeriaanwortel: Valeriaan het 'n wisselwerking met senuoordragstowwe soos GABA, en bring 'n dosisafhanklike vrystelling van GABA teweeg. Valeriaan inhibeer ook die ensiem-geïnduseerde afbreking van GABA in die brein, met gepaardgaande sedasie. Valeriaan se inherente GABA-inhoud kan direk sedasie veroorsaak, hoewel daar besorgdheid is oor biobeskikbaarheid. Daar is gevind dat die valeriaanlignaan hidroksipinoresinol met bensodiasepienreseptore bind. Die valepotriate mag as promiddels werk deur biotransformasie in homobaldrinal deur bakteriële flora. Laastens werk valeriaan se sedatiewe effek meer as 'n senustelseldepressant as 'n spierverslapper.

INDIKASIES
EASY SLEEP 40 WINX word aangedui vir die verligting van matige simptome van geestesspanning en om slaap te bevorder. EASY SLEEP 40 WINX is ontwerp om slaap en ontspanning snags te verbeter en jou 'n energieke hupstoot vir die dag te gee.

KONTRA-INDIKASIES
Hipersensitiwiteit vir enige van die bestanddele, insluitend bindmiddels.
Nie vir gebruik in kinders en jeugdiges onder 18 jaar nie.
EASY SLEEP 40 WINX moet nie gebruik word deur persone wat ly aan:
- enige aandoening geassosieer met hiperkalsemie en hiperkalsiurie, asook by nierontoereikendheid (chronies);
- nier-osteodistrofie met hiperfosfatemie (risiko van metastatiese kalsifisering).
- Wilson se siekte (die aandoening mag vererger word);
- lewer- en galsiekte.

WAARSKUWINGS EN SPESIALE VOORSORG
Neem 2 uur voor of na ander medikasies.
Raadpleeg jou gesondheidskundige as jy 'n lae-proteïen dieet volg.
Raadpleeg 'n dokter as jy vir langer as 3 weke las het van slaaploosheid, as simptome voortduur of erger word.
Gebruik van alkohol, ander medikasies of natuurlike gesondheidsprodukte met sedatiewe eienskappe word nie aanbeveel nie.

Vermoë om te bestuur en met masjinerie te werk
Die Aand-kapsule van EASY SLEEP 40 WINX mag jou vermoë benadeel om 'n voertuig te bestuur en masjinerie te gebruik.

INTERAKSIES
Bisfosfonate: kalsium mag die opname van etidronate verminder.
4-Kinolone: kalsium en magnesium mag die opname van 4-kinolone verminder.
Tamoksifeen: kalsiumaanvullings mag die risiko van hiperkalsemie ('n seldsame newe-effek van tamoksifeenbehandeling) verhoog.
Tetrasikliene: kalsium en magnesium mag die opname van tetrasikliene verminder.
Yster: kalsiumkarbonaat of kalsiumfosfaat mag die opname van yster verminder.
Sink: kalsium mag die opname van sink verminder.
Kalsitonien: die effek van kalsitonien mag deur vitamien D teengewerk word.
Digoksien: wees versigtig want hiperkalsemie wat deur vitamien D veroorsaak word, mag die uitwerkings van digoksien versterk, wat hartritmestoornis tot gevolg kan hê.
Tiasieddiuretika: vitamien D mag die risiko van hiperkalsemie verhoog.
Vitamien D analoë (alfakalsidol, kalsitriol, dihidrotagisterol): verhoogde risiko van toksisiteit met vitamien D aanvullings.

SWANGERSKAP EN LAKTASIE
Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.
Die gebruik van EASY SLEEP 40 WINX tydens swangerskap en laktasie word nie aanbeveel nie.

DOSERING EN GEBRUIKSAANWYSINGS
Vir mondelikse gebruik.
Saans: Neem saans een Deurskynende Aand-kapsule, ongeveer 'n uur voor slapenstyd.
Soggens: Neem een Wit Multivitamien Kapsule met ontbyt.
Neem 2 uur voor of na ander medikasies.

NEWE-EFFEKTE
Mag ligte gastroïntestinale versteurings, bv. naarheid, diarree, hardlywigheid, slegte spysvertering, opgeblaasde maag en winderigheid veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE OOR DIE BEHANDELING DAARVAN
Vitamien D kan (in buitengewone omstandighede) toksisiteit veroorsaak; die veiligheidsgrens is baie gering. Daar bestaan 'n wye verskil in verdraagsaamheid vir vitamien D.
Oormatige inname lei tot hiperkalsemie en die gepaardgaande uitwerkings. Dit sluit lusteloosheid, anoreksie, hardlywigheid, diarree, droë mond, uitputting, hoofpyn, naarheid en braking, dors en swakheid in.
Latere simptome is dikwels met kalsifisering van sagteweefsels geassosieer en sluit in beenpyn, hartritmestoornis, hoë bloeddruk, nierskade (verhoogde urineringsfrekwensie, verminderde urienkonsentrasievermoë; nokturie, proteïenurie), psigose (seldsaam) en gewigsverlies.
As 'n oordosis vermoed word, moet die middel dadelik gestaak word.

IDENTIFIKASIE
Komponent 1: Deurskynende Kapsule gevul met 'n beigekleurige poeier.
Komponent 2: Wit Kapsule gevul met 'n beigekleurige poeier.

AANBIEDING
'n Kartonhouer wat stulpverpakkingstroke met 30 Deurskynende Aand-kapsules en 30 Wit Multivitamien Kapsules bevat.

BERGINGSAANWYSINGS
Bewaar teen 25 °C of benede.
Beskerm teen lig en vog.
Hou die stulpverpakkingstroke in die buitenste karton.
HOU BUITE DIE BEREIK VAN KINDERS

REGISTRASIENOMMER
Moet toegeken word

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
AnaStellar Brands (Edms) Bpk
Boskruin Business Park, Eenheid 15, Noordelike Vleuel, Grondverdieping,
Bosbokweg, Randpark Ridge, 2169, Gauteng, Republiek van Suid-Afrika
+27 (0)11 792 4601

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Julie 2016

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne het nie ten doel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

PASIËNT-INLIGTINGSPAMFLET

SKEDULERINGSTATUS
Moet toegewys word

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
EASY SLEEP 40 WINX Kapsules

Lees hierdie hele pamflet sorgvuldig voordat jy EASY SLEEP 40 WINX begin neem

EASY SLEEP 40 WINX is verkrygbaar sonder 'n doktersvoorskrif, sodat jy 'n ligte toestand kan behandel. Nogtans moet jy EASY SLEEP 40 WINX steeds versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie pamflet. Dit mag nodig wees om hom weer te lees.
- Moenie EASY SLEEP 40 WINX met 'n ander persoon deel nie.
- Vra jou apteker as jy meer inligting of advies nodig het.
- Raadpleeg 'n dokter as jou simptome erger word of nie verbeter nie.

WAT EASY SLEEP 40 WINX BEVAT
EASY SLEEP 40 WINX bestaan uit 2 Komponente:

Komponent 1:

Elke Deurskynende Aand-kapsule bevat:	
Kalsium (verkry van Kalsiumkarbonaat)	80 mg
Kamille (as Kamillepoeier)	50 mg
L-Arginien (verkry van L-Arginienhidrochloried)	10 mg
L-Glutamien (as L-Glutamien)	10 mg
L-Ornitien (as L-Ornitien)	10 mg
Magnesium (verkry van Magnesiumoksied)	80 mg
Passieblom (as Passieblom 4:1 Ekstrak)	25 mg
Valeriaanwortel (as Valeriaanwortel 4:1 Ekstrak)	25 mg
Vitamien D3 (as Cholekalsiferol)	200 IE

Die ander bestanddele is harde-jel plant-kapsule, magnesiumstearaat (plant), mieliestysel, silikondioksied

Komponent 2:

Elke Wit Multivitamien Kapsule bevat:	
Vitamien A (verkry van Vitamien A Asetaat)	500 IE
Vitamien B1 (verkry van Tiamienhidrochloried)	5 mg
Vitamien B2 (as Riboflavien)	5 mg
Vitamien B3 (as Nikotienamied)	10 mg
Vitamien B5 (verkry van Kalsium-D-Pantotenaat)	10 mg
Vitamien B6 (verkry van Piridoksienhidrochloried)	10 mg
Vitamien B12 (verkry van Sianokobalamien)	10 µg
Vitamien C (as Askorbiensuur)	150 mg
Vitamien E (as dl-α-Tokoferol)	10 IE
Biotien (as Biotien)	25 µg
Foliensuur (as Foliensuur)	500 µg
Yster (verkry van Ysteraminosuurchelaat)	15 mg
Inositol (as Mio-Inositol)	25 mg

Die ander bestanddele is harde-jel plant-kapsule, magnesiumstearaat (plant), mieliestysel en silikondioksied.

WAARVOOR EASY SLEEP 40 WINX GEBRUIK WORD
EASY SLEEP 40 WINX word aangedui vir die verligting van matige simptome van geestesspanning en om slaap te bevorder.
EASY SLEEP 40 WINX is ontwerp om slaap en ontspanning snags te verbeter en jou 'n energieke hupstoot vir die dag te gee.

VOORDAT JY EASY SLEEP 40 WINX NEEM
Moet nie EASY SLEEP 40 WINX neem indien:
- Jy hipersensitief (allergies) vir enige van die bestanddele van EASY SLEEP 40 WINX is.
- Jy jonger as 18 jaar is.
- Jy chroniese niersiekte het of hoë kalsiumvlakke in jou bloed of urine het.
- Jy aan nier-osteodistrofie met hiperfosfatemie ly ('n beensiekte wat ontstaan wanneer die niere nie reg werk nie).

Wees bedagsaam wanneer jy EASY SLEEP 40 WINX neem:
Neem EASY SLEEP 40 WINX 2 uur voor of na ander medikasie.
Raadpleeg jou gesondheidskundige as jy 'n lae-proteïen dieet volg.
Spreek 'n dokter as jy vir langer as 3 weke las het van slaaploosheid, of as simptome voortduur of erger word.
Gebruik van alkohol, ander medikasies of natuurlike gesondheidsprodukte met sedatiewe eienskappe word nie aanbeveel nie.

EASY SLEEP 40 WINX saam met kos en dranke:
EASY SLEEP 40 WINX moet saam met kos geneem word.

Swangerskap en borsvoeding:
Daar word nie aanbeveel dat jy EASY SLEEP 40 WINX neem terwyl jy swanger is of borsvoed nie.
As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidskundige voordat jy hierdie middel neem.

Bestuur en gebruik van masjinerie:
Die aandkapsules van EASY SLEEP 40 WINX mag jou lomerig laat voel.

Ander medisyne saam met EASY SLEEP 40 WINX:
Sê altyd vir jou gesondheidskundige as jy enige ander medisyne neem.
Dit sluit gesondheidsaanvullings of tradisionele medisyne in.

Bisfosfonate (in die behandeling van osteoporose gebruik): kalsium mag die opname van etidronate verminder.

4-Kinolone ('n groep antibiotika): kalsium en magnesium mag die opname van 4-kinolone verminder.

Tamoksifeen (in die voorkoming en behandeling van borskanker gebruik): kalsiumaanvullings mag die risiko van hiperkalsemie (hoë kalsiumvlakke in die bloed) verhoog.

Tetrasikliene ('n tipe antibiotika): kalsium en magnesium mag die opname van tetrasikliene verminder.

Yster: kalsiumkarbonaat of kalsiumfosfaat mag die opname van yster verminder.

Sink: kalsium mag die opname van sink verminder.

Kalsitonien ('n hormoon): vitamien D mag teen die effek van kalsitonien werk.

Digoksien ('n middel wat gebruik word om hartversaking te behandel): hoë kalsiumvlakke in die bloed wat deur vitamien D veroorsaak word, mag die uitwerkings van digoksien verhoog, wat kardiale aritmieë (abnormale hartritme) tot gevolg kan hê.

Tiasieddiuretika (medisyne wat gebruik word om hoë bloeddruk en waterretensie/swelsel te behandel): vitamien D mag die risiko van hiperkalsemie (hoë kalsiumvlakke in die bloed) verhoog.

Vitamien D analoë (alfakalsidol, kalsitriol, dihidrotagisterol): verhoogde risiko van toksisiteit met vitamien D aanvullings.

HOE OM EASY SLEEP 40 WINX TE NEEM
Moenie medisyne met iemand anders deel nie.
As jy onseker is oor hoe om EASY SLEEP 40 WINX te gebruik, bespreek dit gerus met jou dokter of apteker.
Die gewone dosis is een deurskynende aand-kapsule, ongeveer 'n uur voor slapenstyd en dan een wit multivitamien kapsule in die oggend met ontbyt.
Neem 2 uur voor of na ander medikasies.

As jy meer EASY SLEEP 40 WINX neem as wat jy behoort:
In die geval van 'n oordosis, kontak jou dokter of apteker.
As nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy 'n EASY SLEEP 40 WINX dosis oorgeslaan het:
Moenie 'n dubbeldosis neem om vir die vergete individuele dosis op te maak nie.

MOONTLIKE NEWE-EFFEKTE
EASY SLEEP 40 WINX kan newe-effekte hê.
Nie alle newe-effekte wat vir EASY SLEEP 40 WINX vermeld is, is in hierdie pamflet ingesluit nie.
As jou algemene gesondheid sou versleg of as jy enige ongewenste uitwerkings ondervind terwyl jy hierdie middel neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidskundige vir professionele advies.
Jy mag (in uitsonderlike gevalle) naarheid, diarree, hardlywigheid, slegte spysvertering, opgeblaasde maag en winderigheid ervaar terwyl jy EASY SLEEP 40 WINX neem.
As jy enige newe-effekte ondervind wat nie in hierdie pamflet genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

BEWARING EN WEGGOOI VAN EASY SLEEP 40 WINX
Hou alle medisyne buite kinders se bereik.
Bewaar teen 25 °C of benede.
Beskerm teen lig en vog.
Hou die stulpverpakkingstroke in die buitenste karton.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN EASY SLEEP 40 WINX
'n Kartonhouer wat stulpverpakkingstroke met 30 Deurskynende Aand-kapsules en 30 Wit Multivitamien Kapsules bevat.

IDENTIFIKASIE VAN EASY SLEEP 40 WINX
Komponent 1: Deurskynende Kapsule gevul met 'n beigekleurige poeier.
Komponent 2: Wit Kapsule gevul met 'n beigekleurige poeier.

REGISTRASIENOMMER
Moet toegeken word

NAAM EN ADRES VAN DIE REGISTRASIEHOUER
AnaStellar Brands (Edms) Bpk
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