

## PACKAGE INSERT

**SCHEDULING STATUS**

To be assigned

**PROPRIETARY NAME AND DOSAGE FORM**  
REPLENI-MAG Tablets and Capsules

**COMPOSITION**

REPLENI-MAG is comprised of 2 Components:

<i><b>Component 1:</b></i>	
<b>Each Orange Magnesium Complex Tablet contains:</b>	
<b>Essential Salts:</b>	
Magnesium (derived from Magnesium Oxide)	150 mg
Calcium (derived from Calcium Carbonate)	75 mg
Potassium (derived from Potassium Phosphate)	40 mg
Sodium (derived from Sodium Chloride)	40 mg
<b>Amino Acids and Derivatives:</b>	
L-Arginine (derived from L-Arginine Hydrochloride)	10 mg
L-Aspartic Acid (as L-Aspartic Acid)	20 mg
L-Carnitine (derived from L-Carnitine Tartrate)	20 mg
L-Glutamine (as L-Glutamine)	10 mg
L-Leucine (as L-Leucine)	10 mg
L-Lysine (as L-Lysine)	10 mg
L-Ornithine (as L-Ornithine)	10 mg
Taurine (as Taurine)	20 mg
<b>Anti-Oxidants:</b>	
Co-Enzyme Q10 (as Co-Enzyme Q10)	5 mg
Copper (derived from Copper Sulphate)	1 mg
Selenium (derived from Selenium Amino Acid Chelate)	15 µg
Zinc (derived from Zinc Oxide)	5 mg
<b>Other Essential Nutrients:</b>	
Vitamin D3 (as Cholecalciferol)	200 IU
Malic Acid (as Malic Acid)	200 mg
Manganese (derived from Manganese Sulphate)	3 mg
Excipients: Flexicoat® orange, magnesium stearate (vegetable), maize starch, microcrystalline cellulose, povidone, shellac, silicon dioxide	

<i><b>Component 2:</b></i>	
<b>Each White Multi-Vitamin Capsule contains:</b>	
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- $\alpha$ -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: 34.12 Multiple substance formulation

**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.

***L-Aspartic acid:*** Aspartic Acid is a non-essential amino acid in humans. It has an overall negative charge and plays an important role in the synthesis of other amino acids and in the citric acid and urea cycles. Asparagine, arginine, lysine, methionine, isoleucine, and some nucleotides are synthesized from aspartic acid. Aspartic acid also serves as a neurotransmitter.

***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.

***L-Carnitine:*** Carnitine regulates long-chain fatty acid transport across cell membranes; facilitates beta-oxidation of long-chain fatty acids and keto acids; and transportation of acyl CoA compounds.

***Co-Enzyme Q10:*** Co-enzyme Q10 is involved in electron transport and supports synthesis of adenosine triphosphate (ATP) in the mitochondrial membrane and thus plays a vital role in intracellular energy production. It is a fat-soluble anti-oxidant that helps to stabilise cell membranes, preserving cellular integrity and function. It also helps to regenerate Vitamin E to its anti-oxidant form. It has immune-stimulant activity.

***Copper:*** Copper functions as an essential component of several enzymes (e.g. superoxide dismutase) and other proteins. It plays a role in bone formation and mineralisation, and in the integrity of the connective tissue of the cardiovascular system. Copper has pro-oxidant effects in vitro but antioxidant effects in vivo; there is accumulating evidence that adequate copper is required to maintain antioxidant effects within the body.

***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).

***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.

***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, deoxyribonucleic acid (DNA) synthesis and catecholamine metabolism.

***L-Leucine:*** Leucine is a branched chain amino acid which is an essential amino acid. The primary function of branched chain amino acids is as precursors for the synthesis of proteins. In addition, they may be broken down if necessary to serve as an energy source.

***L-Lysine:*** L-lysine, is an essential amino acid, and is important for proper growth. It plays an essential role in the production of carnitine, a nutrient responsible for converting fatty acids into energy and helping lower cholesterol. Lysine appears to help the body absorb calcium, and it plays an important role in the formation of collagen.

***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 deoxyribonudeic acid (DNA); neuromuscular transmission; and calcium metabolism.

***Malic acid:*** Malic acid is a naturally occurring compound that plays a role in the complex process of deriving adenosine triphosphate (ATP) from food.

***Manganese:*** Manganese activates several enzymes, including hydroxylases, kinases, decarboxylases and transferases. It is also a constituent of several metalloenzymes, such as arginase, pyruvate carboxylase, and also superoxide dismutase, which protects cells from free radical attack. It may have a role in the regulation of glucose homeostasis and in calcium mobilisation.

***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.

***Potassium:*** Potassium is the principal intracellular cation, and is fundamental to the regulation of acid-base and water balance. It contributes to transmission of nerve impulses, control of skeletal muscle contractility and maintenance of blood pressure.

***Selenium:*** Selenium functions as an integral part of the enzyme glutathione peroxidase and other selenoproteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes. Selenium spares the requirement for vitamin E and vice versa.

***Sodium:*** Sodium is one of the principle ions in extracellular fluid. It plays a role in the maintenance of membrane potential and is a primary determinant of blood volume and blood pressure.

***Taurine:*** Taurine is an organic osmolyte involved in cell volume regulation, and provides a substrate for the formation of bile salts. It plays a role in the modulation of intracellular free calcium concentration. Taurine serves a wide variety of functions in the central nervous system, from development to cytoprotection.

***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.

***Zinc:*** Zinc is an essential component of over 200 enzymes. It plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein.

**INDICATIONS**  
REPLENI-MAG is indicated to help prevent and ease muscle cramps and spasms.

**CONTRAINDICATIONS**  
Hypersensitivity to any of the ingredients, including excipients. Not for use in children and adolescents below the age of 18 years. REPLENI-MAG 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.

**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 REPLENI-MAG during pregnancy and lactation is not recommended.

**DOSAGE AND DIRECTIONS FOR USE**  
For oral use.  
Morning: Take one White Multi-Vitamin Capsule with Breakfast.  
Evening: Take one Orange Magnesium Complex Tablet with Dinner.  
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.  
Zinc supplementation may cause a copper deficiency.

**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:*** Orange Oval Film-coated Tablet.  
***Component 2:*** White Capsule filled with a beige coloured powder.

**PRESENTATION**  
A cardboard carton containing blister strips of 30 Orange Magnesium Complex Tablets 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 unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

To be assigned

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**  
REPLENI-MAG Tablets and Capsules

**Read all of this leaflet carefully before you start taking REPLENI-MAG**

REPLENI-MAG is available without a doctor’s prescription, for you to treat a mild condition. Nevertheless you still need to use REPLENI-MAG carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share REPLENI-MAG 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 REPLENI-MAG CONTAINS**  
REPLENI-MAG is comprised of 2 Components:

<i><b>Component 1:</b></i>	
<b>Each Orange Magnesium Complex Tablet contains:</b>	
<b>Essential Salts:</b>	
Magnesium (derived from Magnesium Oxide)	150 mg
Calcium (derived from Calcium Carbonate)	75 mg
Potassium (derived from Potassium Phosphate)	40 mg
Sodium (derived from Sodium Chloride)	40 mg
<b>Amino Acids and Derivatives:</b>	
L-Arginine (derived from L-Arginine Hydrochloride)	10 mg
L-Aspartic Acid (as L-Aspartic Acid)	20 mg
L-Carnitine (derived from L-Carnitine Tartrate)	20 mg
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L-Ornithine (as L-Ornithine)	10 mg
Taurine (as Taurine)	20 mg
<b>Anti-Oxidants:</b>	
Co-Enzyme Q10 (as Co-Enzyme Q10)	5 mg
Copper (derived from Copper Sulphate)	1 mg
Selenium (derived from Selenium Amino Acid Chelate)	15 µg
Zinc (derived from Zinc Oxide)	5 mg
<b>Other Essential Nutrients:</b>	
Vitamin D3 (as Cholecalciferol)	200 IU
Malic Acid (as Malic Acid)	200 mg
Manganese (derived from Manganese Sulphate)	3 mg
The other ingredients are Flexicoat® orange, magnesium stearate (vegetable), maize starch, microcrystalline cellulose, povidone, shellac, silicon dioxide	

<i><b>Component 2:</b></i>	
<b>Each White Multi-Vitamin Capsule contains:</b>	
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- $\alpha$ -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, silicon dioxide	

**WHAT REPLENI-MAG IS USED FOR**  
REPLENI-MAG is indicated to help prevent and ease muscle cramps and spasms.

**BEFORE YOU TAKE REPLENI-MAG**  
**Do not take REPLENI-MAG if:**

- Hypersensitive (allergic) to any of the ingredients of REPLENI-MAG.
- 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 REPLENI-MAG:**  
Take REPLENI-MAG 2 hours before or after taking any medication. Consult your healthcare professional if you are following a low protein diet.

**Taking REPLENI-MAG with food and drink:**  
REPLENI-MAG should be taken with food.

**Pregnancy and breastfeeding:**  
It is not recommended to take REPLENI-MAG 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.

**Taking other medicines with REPLENI-MAG:**  
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 REPLENI-MAG**  
Do not share medicines with any other person. You should check with your doctor or pharmacist if you are unsure on how to use REPLENI-MAG. The usual dose is one white multi-vitamin capsule in the morning with breakfast and then one orange magnesium complex tablet in the evening with dinner. Take 2 hours before or after taking other medications.

**If you take more REPLENI-MAG than you should:**  
In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you missed a dose of REPLENI-MAG:**  
Do not take a double dose to make up for a forgotten individual dose.

**POSSIBLE SIDE EFFECTS**  
REPLENI-MAG can have side effects. Not all side effects reported for REPLENI-MAG 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 experience nausea, diarrhoea, constipation, indigestion, bloating and flatulence while taking REPLENI-MAG.

Zinc supplementation may cause a copper deficiency. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**STORING AND DISPOSING OF REPLENI-MAG**  
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 REPLENI-MAG**  
A cardboard carton containing blister strips of 30 Orange Magnesium Complex Tablets and 30 White Multi-Vitamin Capsules.

**IDENTIFICATION OF REPLENI-MAG**  
***Component 1:*** Orange Oval Film-coated Tablet.  
***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,  
Gauteng, Republic of South Africa  
+27 (0)11 792 4601

**DATE OF PUBLICATION**  
July 2016

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



## VOUBILJET

SKEDULERINGSTATUS

Moet toegewys word

<p><b>EIENDOMSNAAM EN DOSERINGSVORM</b></p> <p>REPLENI-MAG Tablette en Kapsules</p>																																							
<p><b>SAMESTELLING</b></p> <p>REPLENI-MAG bestaan uit 2 Komponente:</p>																																							
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L-Ornitien (as L-Ornitien)	10 mg																																						
Tourien (as Tourien)	20 mg																																						
Ko-Ensiem Q10 (as Ko-Ensiem Q10)	5 g																																						
Koper (verkry van Kopersulfaat)	1 mg																																						
Seleen (verkry van Seleenaminoasuurchelaat)	15 µg																																						
Sink (verkry van Sinkoksied)	5 mg																																						
Vitamiem D3 (as Cholekalsiferol)	200 IE																																						
Appelsuur (as Appelsuur)	20 mg																																						
Mangaan (verkry van Mangaansulfaat)	3 mg																																						

<p><b>Komponent 2:</b></p> <p><b>Elke Wit Multivitaminien Kapsule bevat:</b></p> <p>Vitamiem A (verkry van Vitamiem A Asetaat)</p> <p>Vitamiem B1 (as Tiamienhidrochloried)</p> <p>Vitamiem B2 (as Riboflaviem)</p> <p>Vitamiem B3 (verkry van Nikotienamied)</p> <p>Vitamiem B5 (verkry van Kalsium-D-Pantotenaat)</p> <p>Vitamiem B6 (verkry van Piridoksienhidrochloried)</p> <p>Vitamiem B12 (verkry van Sianokobalamien)</p> <p>Vitamiem C (as Askorbiensuur)</p> <p>Vitamiem E (as dl-α-Tokoferol)</p> <p>Biotien (as Biotien)</p> <p>Foliensuur (as Foliensuur)</p> <p>Yster (verkry van Ysteraminoasuurchelaat)</p> <p>Inositol (as Mio-Inositol)</p> <p>200 IE</p> <p>5 mg</p> <p>5 mg</p> <p>10 mg</p> <p>10 mg</p> <p>10 µg</p> <p>150 mg</p> <p>10 IE</p> <p>25 µg</p> <p>500 µg</p> <p>15 mg</p> <p>25 mg</p>	
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Bindmiddels: Flexicoat®oranje, magnesiumstearaat (plant), mieliestysel, mikrokristallyne sellulose, povidoon, skellak, silikondioksied

<p><b>Komponent 2:</b></p> <p><b>Elke Wit Multivitaminien Kapsule bevat:</b></p> <p>Vitamiem A (verkry van Vitamiem A Asetaat)</p> <p>Vitamiem B1 (as Tiamienhidrochloried)</p> <p>Vitamiem B2 (as Riboflaviem)</p> <p>Vitamiem B3 (verkry van Nikotienamied)</p> <p>Vitamiem B5 (verkry van Kalsium-D-Pantotenaat)</p> <p>Vitamiem B6 (verkry van Piridoksienhidrochloried)</p> <p>Vitamiem B12 (verkry van Sianokobalamien)</p> <p>Vitamiem C (as Askorbiensuur)</p> <p>Vitamiem E (as dl-α-Tokoferol)</p> <p>Biotien (as Biotien)</p> <p>Foliensuur (as Foliensuur)</p> <p>Yster (verkry van Ysteraminoasuurchelaat)</p> <p>Inositol (as Mio-Inositol)</p> <p>500 IE</p> <p>5 mg</p> <p>5 mg</p> <p>10 mg</p> <p>10 mg</p> <p>10 µg</p> <p>150 mg</p> <p>10 IE</p> <p>25 µg</p> <p>500 µg</p> <p>15 mg</p> <p>25 mg</p>	
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Bindmiddels: harde-jel plant-kapsule, magnesiumstearaat (plant), mieliestysel, silikondioksied

**FARMAKOLOGIESE KLASSIFIKASIE**  
D: 34.12 Multistof-formulering

**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 proteiene (as 'n deel van die strukture), en groeihormoonvrystelling.

***L-Aspartiensuur:*** Aspartiensuur is 'n nie-essensiële aminosuur in die mens. Dit het 'n totale negatiewe lading en speel 'n belangrike rol in die sintese van ander aminosure en in die sitroënsuur- en ureumsiklusse. Asparagine, arginien, lisien, metionien, isoleusien, en sommige nukleotiede word van aspartiensuur gesintetiseer. Aspartiensuur dien ook as 'n senuoordragstof.

***Biotien:*** Biotien funksioneer as 'n integrale deel van die ensieme wat karkboksieleenhede 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.

***L-Karnitien:*** Karnitien reguleer langketting-vetsuurvervoer o selmembraan; dit bevorder beta-oksidasie van langketting-vetsure en ketosure; asook vervoer van asiel KoA-verbindings.

***Ko-Ensiem Q10:*** Ko-Ensiem Q10 is by elektronvervoer betrokke en ondersteun sintese van adenosientrifosfaat (ATP) in die mitokondriese membraan en speel dus 'n uiters noodsaaklike rol in intrasellulêre energieproduksie. Dit is 'n vetoplosbare antioksidant en help om selmembraan te stabiliseer, wat sellulêre integriteit en funksie bewaar. Dit help ook om Vitamiem E tot sy antioksidantvorm te regeneer. Dit het immuunstimulant-aktiwiteit.

***Koper:*** Koper funksioneer as 'n essensiële komponent van 'n aantal ensieme (bv. superoksieddismutase) en ander proteiene. Dit speel 'n rol in beenvorming en mineralisasie, en in die integriteit van die bindweefsel van die kardiovaskulêre stelsel. Koper het pro-oksidant effekte in vitro maar antioksidant-effekte in vivo; daar is toenemende bewys dat voldoende koper nodig is om antioksidant-effekte in die liggaam in stand te hou.

***Foliensuur:*** Foliensuur is by 'n aantal enkelkoolstof-ordrareaksies betrokke, veral in die sintese van puriene en pirimidiene (en gevolglik die sintese van deoksiribonukleiensuur (DNA)), glisien en metionien. Hulle is ook by sommige aminosuorumsettings en in die vorming en benutting van formaat betrokke. 'n Tekort lei tot belemmerde selverdeling (die uitwerkings is mees merkbaar by weefsel wat vinnig regeneer).

***L-Glutamien:*** Soos ander aminosure is glutamien biochemies belangrik as 'n bestanddeel van proteiene. 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 verbindinge, insluitend ander aminosure, puriene, en pirimidiene.

***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, deoksiribonukleiensuur-(DNA) sintese en katesjolumienmetabolisme.

***L-Leusien:*** L-Leusien is 'n vertakteketting-aminosuur wat 'n essensiële aminosuur is. Die primêre funksie van vertakteketting-aminosure is as voorlopers vir die sintese van proteiene. Daarby kan hulle afgebreek word indien nodig om as 'n energiebron te dien.

***L-Lisien:*** L-Lisien is 'n essensiële aminosuur, en is belangrik vir behoorlike groei. Dit speel 'n noodsaaklike rol in die produksie van karnitien, 'n voedingstof wat daarvoor verantwoordelik is om vetsure in energie om te sit en wat help om cholesterol te verlaag. Dit blyk dat karnitien die liggaam help om cholesterol op te neem, en dit speel 'n belangrike rol in die vorming van kollageen.

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

***Appelsuur:*** Appelsuur is 'n verbinding wat natuurlik voorkom en dit speel 'n rol in die komplekse proses om adenosientrifosfaat (ATP) uit voedsel te verkry.

***Mangaan:*** Mangaan aktiveer 'n aantal ensieme, insluitend hidrosilases, kinases, dekarboksilasies en transferases. Dit is ook 'n bestanddeel van etlike metalloënsieme, soos arginase, piruvaatkarboksilase, en ook superoksieddismutase, wat selle teen vryradikaalaanval beskerm. Dit mag 'n rol in die regulering van glukosehomeostase en in kalsiummobilisasie hê.

***L-Ornitien:*** Ornitien is 'n nie-essensiële en nie-proteien aminosuur en is van kritieke belang vir die produksie van die liggaam se proteiene, ensieme en spierweefsel. Ornitien speel 'n sentrale rol in die ureumsiklus en is belangrik vir die opruiwing van 'n oormaat stikstof (ammoniak). Ornitien is die beginpunt vir die sintese van talle poliamiene soos putresien en spermiem.

***Kalium:*** Kalium is die hoof-intrasellulêre kation, en is fundamenteel tot die regulering van suurbasis en waterbalans. Dit dra by tot die oordrag van senu-impulse, beheer van skeletspier-saamtrekbaarheid en instandhouding van bloeddruk.

***Seleen:*** Seleen funksioneer as 'n integrale deel van die ensiem glutatioonperoksidase en ander selenoproteiene. Glutatioonperoksidase word in die ontwikkeling van suurstof-vryradikale wat die vernietiging van pol-ondersadigde vetsure in selmembraan veroorsaak. Seleen spaar die behoefte aan Vitamiem E en omgekeerd.

***Natrium:*** Natrium is een van die hoof-ione in buitesellulêre vloeistof. Dit speel 'n rol in die instandhouding van membraanpotensiaal en is 'n primêre determinant van bloedvolume en bloeddruk.

***Tourien:*** Tourien is 'n organiese osmoliet wat by selvolumeregulering betrokke is, en voorsien 'n substraat vir die vorming van galsoute. Dit speel 'n rol in die modulering van intrasellulêre vry kalsiumkonsentrasie. Tourien verkig 'n wye verskeidenheid funksies in die sentrale senuweestelsel, van ontwikkeling tot sitobeskerming.

***Vitamiem A:*** Vitamiem A (in die vorm van retinaal) is noodsaaklik vir normale funksie van die retina, veral vir visuele aanpassing by donkerste. 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. Vitamiem A mag as 'n kofaktor in biochemiese reaksies optree.

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

***Vitamiem B2:*** Riboflavin het 'n rol as 'n komponent van twee flavienkoënsieme – flavienmonokleotied (FMN) en flavienadienidinkleotied (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. Ribovlavin het 'n rol as 'n antioksidant. Dit mag betrokke wees by die instandhouding van die integriteit van eritrosiete.

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

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

***Vitamiem B6:*** Vitamiem 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 proteien, lipied- en koolhidraatmetabolisme beïnvloed. Paradoksaalfosfaat is ook teenwoordig in die sintese van etlike senuoordragstowwe; die metabolisme van 'n aantal vitamieni (bv. die omsetting van triptofaan in niasien); en hemoglobien- en sfingosienvorming.

***Vitamiem B12:*** Vitamiem B12 is aktief in die herbenutting van folaatkoënsieme en die afbreking van valien. Dit is ook nodig vir senuweemiëlinering, selepklisasie, hematopoiese en nukleoproteïensintese.

***Vitamiem 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 intersellulêre matrys in been, tande en haarvate; en die optimale werking van etlike ensieme. Vitamiem 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.

***Vitamiem D:*** Vitamiem 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.

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

***Sink:*** Sink is 'n essensiële komponent van meer as 200 ensieme. Dit speel 'n belangrike rol in die metabolisme van proteiene, koolhidrate, lipiede en nukleiensure. Dit is 'n kofaktor in 'n reeks biochemiese prosesse, insluitend die sintese van DNA, RNA en proteïene.

**INDIKASIE**  
REPLENI-MAG word aangedui om spierkrampe en spasmas te help voorkom en te verlig.

**KONTRA-INDIKASIE**  
Hipersensitiwiteit vir enige van die bestanddele, insluitend bindmiddels. Nie vir gebruik in kinders en jeugdiges onder 18 jaar nie. REPLENI-MAG moet nie gebruik word deur persone wat ly aan:

- enige aandoening geassosieer met hiperkalsemie en hiperkalsurie, asook by nierontoereikendheid (chronies);
- nier-osteodistrofie met hiperfosfatemie (risiko van metastatiese kalsifisering).
- Wilson se siekte (die aandoening mag vererger word);
- liewer- en galsiekte.

**WAARSKUWINGS EN SPESIALE VOORSORG**  
Neem 2 uur voor of na ander medikasies. Raadpleeg jou gesondheidskundige as jy 'n lae-proteïen dieet volg.

**INTERAKSIE**  
***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 hartritmestormis tot gevolg kan hê.
***Tiasieddiuretika:*** vitamien D mag die risiko van hiperkalsemie verhoog.
***Vitamiem 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 REPLENI-MAG tydens swangerskap en laktasie word nie aanbeveel nie.

**DOSERING EN GEBRUIKSAANWYSINGS**  
Vir mondellike gebruik.
Soggens: Neem een Wit Multivitaminien Kapsule met Ontbyt.
Saans: Neem een Oranje Magnesiumkompleks Tablet met Aandete.
Neem 2 uur voor of na ander medikasies.

**NEWE-EFFEKTE**  
Mag ligte gastroïntestinale versteurings, bv. naarheid, diarree, hardlywigheid, slegte spysvertering, opgeblaasde maag en widerigheid veroorsaak.
Sinkaanvulling mag 'n gebrek aan koper veroorsaak.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE OOR DIE BEHANDELING DAARVAN**
Vitamiem 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, hartritmestormis, hoë bloeddruk, nierskade (verhoogde urineringsfrekwensie, verminderde urienkonsentrasievermoë; nokturie, proteïenuurie), psigose (seldsaam) en gewigsverlies. As 'n oordosis vermoed word, moet die middel dadelik gestaak word.

**IDENTIFIKASIE**  
***Komponent 1:*** Oranje Ovaal Filmbedekte Tablet.
***Komponent 2:*** Wit Kapsule gevul met 'n beigekleurige poeier.

**AANBIEDING**  
'n Kartonhouer wat stulperpakkingstrok met 30 Oranje Magnesiumkompleks Tablette en 30 Wit Multivitaminien Kapsules bevat.

**BERGINGSAAANWYSINGS**  
Bewaar teen 25 °C of benede.
Beskerm teen lig en vog.
Hou die stulperpakkingstrok in die buitenste karton.
**HOU BUITE DIE BEREK VAN KINDERS**

**REGISTRASIENOMMER**  
Moet toegeken word

**NAAM EN BESIGHEIDSDRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFKAAT**
AnaStellar Brands (Edms) Bpk
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Gauteng, Republiek van Suid-Afrika
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**DATUM VAN PUBLIKASIE VAN DIE VOUBILJET**  
Julie 2016

Hierdie ongeregistreeerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

## PASIËNT-INLIGTINGSPAMFLET

SKEDULERINGSTATUS

Moet toegewys word

<p><b>EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM</b></p> <p>REPLENI-MAG Tablette en Kapsules</p>																																							
<p><b>Lees hierdie hele pamflet sorgvuldig voordat jy REPLENI-MAG begin neem</b></p>																																							
<p>REPLENI-MAG is verkrygbaar sonder 'n doktersvoorskrif, sodat jy 'n ligte toestand kan behandel. Nogtans moet jy REPLENI-MAG steeds versigtig gebruik om die beste resultate daaruit te kry.</p> <ul style="list-style-type: none"><li>Hou hierdie pamflet. Dit mag nodig wees om hom weer te lees.</li> <li>Moenie REPLENI-MAG met 'n ander persoon deel nie.</li> <li>Vra jou apteker as jy meer inligting of advies nodig het.</li> <li>Raadpleeg 'n dokter as jou simptome erger word of nie verbeter nie.</li></ul>																																							
<p><b>WAT REPLENI-MAG BEVAT</b></p> <p>REPLENI-MAG bestaan uit 2 Komponente:</p>																																							
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**WAARVOOR REPLENI-MAG GEBRUIK WORD**  
REPLENI-MAG word aangedui om spierkrampe en spasmas te help voorkom en te verlig.