BlemiMETICS™ Film-coated Tablets

PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

SCHEDULING STATUS

To be assigned

1. NAME OF THE MEDICINE

BlemiMETICS™ Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BlemiMETICS™ is comprised of 2 components:

Component 1:

Each White Tablet contains

Vitamin A derived from Vitamin A Acetate 2 mg	**1 000**	**IU**
Vitamin C derived from Ascorbic Acid 200 mg	**200**	**mg**
Vitamin D3 derived from Cholecalciferol 10 mg	**1 000**	**IU**
Vitamin E derived from dl-α-Tocopherol Acetate 30 mg	**20**	**IU**
Biotin	**500**	**µg**
Calcium derived from Calcium Carbonate 200 mg	**80**	**mg**
Copper derived from Copper Sulphate 4 mg	**1**	**mg**
Folate derived from (6S)-5-Methyltetrahydrofolate 226 µg	**200**	**µg**
Magnesium derived from Magnesium Oxide 133 mg	**80**	**mg**
Zinc derived from Zinc Oxide 25 mg	**20**	**mg**

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

Sucrose, Lactose, Gluten and Tartrazine Free.

Component 2:

Each Yellow Tablet contains

Vitamin B3 derived from Niacinamide 30 mg	**30**	**mg**
Vitamin B5 derived from Calcium-d-Pantothenate 218 mg	**200**	**mg**
Inositol derived from Myo-Inositol 400 mg D-Chiro-Inositol 10 mg	**410**	**mg**

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

Sucrose, Lactose, Gluten and Tartrazine Free.

3. PHARMACEUTICAL FORM

Film-coated Tablets.

Component 1
White Oval shaped Film-coated Tablets.

Component 2
Yellow Oval shaped Film-coated Tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BlemiMETICS™ is a health supplement intended as nutritional support to aid clear skin in adults and children from the age of 14 years.

4.2 Posology and method of administration

For oral use.

Take one BlemiMETICS™ White Film-coated Tablet and one Yellow Film-coated Tablet daily in the Morning with Breakfast.

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 excipients listed in section 6.1.

BlemiMETICS™ 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).

4.4 Special warnings and precautions for use

The indicated daily dosage should not be exceeded.

High dose zinc supplementation may cause a copper or iron deficiency.

Vitamin D may increase the risk of hypercalcaemia.

Not suitable for children below the age of 14 years (due to the Vitamin B3 content) unless under the direct supervision of a qualified healthcare professional.

4.5 Interactions with other medicines

Alcohol: may increase renal excretion of magnesium.

Bisphosphonates: calcium may reduce absorption of etidronate.

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.

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

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

Tetracyclines: magnesium and zinc may reduce absorption of tetracyclines if not taken 2 hours apart.

Thiazide diuretics: vitamin D may increase risk of hypercalcaemia and may increase excretion of magnesium.

Zinc: may cause a reduced absorption of ciprofloxacin and penicillamine and calcium may reduce absorption of zinc.

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 before taking any medicines if you are pregnant, planning to have a baby or breastfeeding.

The ingredients in BlemiMETICS™ are commonly included in pregnancy products.

4.7 Effects on ability to drive and use of machines

None.

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 transmission, enzyme activation and hormone function.

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.

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 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.

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.

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 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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component 1:
Tablet Core:
Calcium Phosphate Dibasic
Magnesium Stearate
Povidone
Silicon Dioxide
Sodium Starch Glycolate
Solvent 45

Tablet Coating:
Castor Oil
Flexicoat
Shellac

Component 2:
Tablet Core:
Calcium Phosphate Dibasic
Magnesium Stearate
Povidone
Silicon Dioxide
Sodium Starch Glycolate
Solvent 45

Tablet Coating:
Castor Oil
Flexicoat
Shellac

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 White Oval shaped Film-coated Tablets contained in 3 x PVC/PVDC/Aluminium blister strips.

Component 2:
10 x Yellow Oval shaped Film-coated Tablets contained in 3 x PVC/PVDC/Aluminium blister strips.

Packed product:
6 x Blister strips enclosed within a cardboard carton.
Pack size of 30 x White Film-coated Tablets of Component 1 and 30 x Yellow Film-coated Tablets of Component 2.

6.6 Special precautions for disposal

No special requirements.

7. Holder of 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

8. Registration number

TBC

9. Date of first authorisation

TBC

10. Date of revision of the text

January 2023