

# AgeMETICS™ Film-coated Tablets

## PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

### SCHEDULING STATUS

To be assigned

### 1. NAME OF THE MEDICINE

AgeMETICS™ Film-coated Tablets

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

AgeMETICS™ is comprised of 2 components:

#### Component 1:

Each White Tablet contains

<b>Vitamin A</b> derived from Vitamin A Acetate 2 mg	1 000	IU
<b>Vitamin C</b> derived from Ascorbic Acid 200 mg	200	mg
<b>Vitamin D3</b> derived from Cholecalciferol 10 mg	1 000	IU
<b>Vitamin E</b> derived from dl- $\alpha$ -Tocopherol Acetate 30 mg	20	IU
<b>Biotin</b>	500	$\mu$ g
<b>Calcium</b> derived from Calcium Carbonate 200 mg	80	mg
<b>Copper</b> derived from Copper Sulphate 4 mg	1	mg
<b>Folate</b> derived from (6S)-5-Methyltetrahydrofolate 226 $\mu$ g	200	$\mu$ g
<b>Magnesium</b> derived from Magnesium Oxide 133 mg	80	mg
<b>Zinc</b> 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 Red Tablet contains

<b>Coenzyme Q10</b> derived from Ubidecarenone 50 mg	50	mg
<b>Type I Hydrolysed Collagen</b> [Marine]	1 000	mg
<b>L-Arginine</b> derived from L-Arginine Hydrochloride 60 mg	50	mg
<b>MSM (Methylsulphonylmethane)</b>	50	mg
<b>Selenium</b> derived from Selenium Glycinate 1,5 mg	30	$\mu$ g
<b>Silicon</b> derived from Silicon Amino Acid Chelate 50 mg	2,5	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

Red Oval shaped Film-coated Tablets.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

AgeMETICS™ is a health supplement intended as nutritional support to aid maturing skin in adults.

#### 4.2 Posology and method of administration

For oral use.

Take one AgeMETICS™ White Film-coated Tablet and two Red Film-coated Tablets daily in the Morning with Breakfast.

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

Take with food, 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.

AgeMETICS™ 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);
- a heart attack/myocardial infarction.
- a Fish Allergy.

#### 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 to be taken at bedtime, due to the MSM content.

Consult a relevant healthcare professional:

- prior to use if you are pregnant or breastfeeding;
- if you have a cardiovascular condition and it worsens;
- prior to use if you have a renal/kidney disease or if you are following a low protein diet;
- if you suffer from a cardiovascular disease and are attempting an increase in physical activity;
- prior to use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners.

AgeMETICS™ should not be given to children below the age of 18 years (due to the L-Arginine, Selenium, MSM and Silicon 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, dihydrotychsterol):* 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 safety of L-Arginine as contained in AgeMETICS™ during pregnancy has not been established.

#### 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.

**Coenzyme Q10:** Coenzyme 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 antioxidant that helps to stabilise cell membranes, preserving cellular integrity and function. It also helps to regenerate Vitamin E to its antioxidant form. It has immune-stimulant activity.

**Collagen (hydrolysed Type 1):** Hydrolysed collagen is a source of essential and non-essential amino acids which are involved in protein and collagen synthesis.

**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).

**L-Arginine:** A non-essential amino acid which can be synthesised by the body and serves many functions to create optimal health.

**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.

**Methylsulphonylmethane (MSM):** MSM is a naturally occurring organosulfur molecule and a putative methyl donor. MSM is the first oxidized metabolite of dimethylsulfoxide (DMSO). Because of MSM's sulphur content, it is used by the body to maintain normal connective tissues.

**Selenium:** Selenium functions as an integral part of the enzyme glutathione peroxidase and other seleno-proteins. Glutathione peroxidase prevents the generation of oxygen free radicals that cause the destruction of polyunsaturated fatty acids in cell membranes.

**Silicon:** Silicon is involved in the formation of bones and connective tissues.

**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 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 Red Oval shaped Film-coated Tablets contained in 6 x PVC/PVDC/Aluminium blister strips.

#### Packed product:

9 x Blister strips enclosed within a cardboard carton.  
Pack size of 30 x White Film-coated Tablets of Component 1 and 60 x Red 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

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