

## PROFESSIONAL INFORMATION

Complementary Medicine – Health Supplement

### SCHEDULING STATUS

To be assigned

#### 1. NAME OF THE MEDICINE

VIRAVANCE™ film-coated tablet

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

L-Lysine Hydrochloride providing Lysine 500 mg	625	mg
Ascorbic Acid (Vitamin C)	500	mg
Pyridoxine Hydrochloride (Vitamin B6) providing Pyridoxine 50 mg	61	mg
Zinc Oxide providing Zinc 25 mg	31	mg
Nicotinamide (Vitamin B3)	25	mg
Cholecalciferol providing Vitamin D3 1 000 IU	10	mg
Selenium Amino Acid Chelate providing Selenium 60 µg	3	mg
(6S)-5-Methyltetrahydrofolate providing Folate 400 µg	452	µg
Methylcobalamin (Vitamin B12)	50	µg

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

Suitable for use by Vegetarians  
Sucrose, Lactose, Gluten and Tartrazine Free

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Film-coated tablets.  
Red oblong film-coated tablet.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

VIRAVANCE™ is intended to support the immune system of adults and may also be of benefit in the following conditions:

- Recurrent cold sores
- Canker sores
- Genital herpes
- Angular stomatitis/chellitis.

VIRAVANCE™ can be used by adults to supplement antiviral treatments as well as be used by immunosuppressed patients.

##### 4.2 Posology and method of administration

For oral use.

Take one tablet daily.

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.

##### 4.4 Special warnings and precautions for use

The indicated daily dose should not be exceeded.

Not suitable for children below the age of 18 years unless under the direct supervision of a relevant healthcare professional.

##### 4.5 Interactions with other medicines

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

##### 4.6 Fertility, Pregnancy and Breastfeeding

Always check with your Doctor or Pharmacist before taking any medicines if you are pregnant or breastfeeding.  
The safety of L-Lysine during fertility, pregnancy and breastfeeding 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

**Folate:** Folate is involved in the synthesis of purines and pyrimidines, which are constituents of DNA, as well as the synthesis of amino acids glycine and methionine. Deficiency leads to impaired cell division.

**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.

**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 B6:** Vitamin B6 is converted to pyridoxal phosphate and pyridoxamine phosphate in erythrocytes. It is a cofactor for more than 100 reactions involved in the metabolism of carbohydrates, lipids and protein. Pyridoxal phosphate is also involved in the synthesis of neurotransmitters and metabolism of other vitamins (e.g., conversion of tryptophan to niacin (vitamin B3)).

**Vitamin B12:** Involved in the recycling of coenzymes responsible for folate metabolism. Also involved in the degradation of Valine, an amino acid constituent of most protein.

**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 – it activates certain liver detoxifying enzyme systems (including drug-metabolising enzymes) and is involved in the synthesis of carnitine and noradrenaline and the metabolism of folic acid, histamine, phenylalanine, tryptophan and tyrosine. 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.

**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. It has additional effects, particularly in relation to the immune response and cancer prevention, which are not entirely due to these enzymatic functions.

**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

<u>Tablet Core:</u>	<u>Tablet Coating:</u>
Magnesium Stearate	Castor oil
Maize Starch	Flexicoat bright red V3 PHA5013
Povidone K	Shellac
Silicon Dioxide	
Sodium Starch Glycolate	

##### 6.2 Incompatibilities

None.

##### 6.3 Shelf life

2 years.

##### 6.4 Special precautions for storage

Store at or below 25 °C.  
Keep in the original container until required for use.  
Protect from moisture.

##### 6.5 Nature and contents of container

10 tablets contained in each of 3 x PVC/PVDC/Aluminium blister strips.  
3 x Blister strips enclosed within a cardboard carton.

##### 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  
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#### 8. Registration number

To be assigned

#### 9. Date of first authorisation

Not applicable

#### 10. Date of revision of the text

April 2021

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