### PROFESSIONAL INFORMATION LEAFLET (ENGLISH)

### SCHEDULING STATUS:

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### PROPRIETARY NAME AND DOSAGE FORM CAMED Immune Defense capsules.

### COMPOSITION:

Each CAMED Immune Defense capsule contains:

Active Substance	Per capsule:
Ascorbic acid (Vitamin C)	100 mg
Beta-1,3/1,6 glucan	24 mg
Nicotinamide (Vitamin B3)	16 mg
d-Alpha Tocopheryl Acetate (Vitamin E)	15 mg α-TE (22,35 IU)
Zinc Acetate	35,08 mg
Providing Zinc	12,5 mg
Calcium d-Pantothenate	5,45 mg
Providing Vitamin B5	5 mg
Pyridoxine hydrochloride	2,07 mg
Providing Vitamin B6	1,7 mg
Riboflavin (Vitamin B2)	1,3 mg
Thiamine hydrochloride	1,52 mg
Providing Vitamin B1	1,2 mg
Retinyl Acetate	0,86 mg
Providing Vitamin A	750 µg RE (2500 IU)
Folic acid	250 µg
Selenium Glycinate	287,59 µg
Providing Selenium	100 µg
Biotin	30 µg
Cholecalciferol (Vitamin D3)	12,5 µg (500 IU)
Cyanocobalamin (Vitamin B12)	2,4 µg

The inactive ingredients are a capsule shell (Bovine Gelatine), magnesium stearate, microcrystalline cellulose and talc.

CAMED Immune Defense is sugar free.

## **CATEGORY AND CLASS:**

D.34.12. Multiple substance formulation.

### PHARMACOLOGICAL ACTION:

# Pharmacokinetic properties:

Several vitamins and minerals are needed by the human body to maintain an optimal nutritional status, including a healthy immune system. These vitamins and minerals serve as essential nutrients and support health through several physiological, structural and functional roles.

# Vitamin C:

Serves as an antioxidant and protects cells from oxidative stress. It also contributes to the normal function of the immune system by increasing the production of T-lymphocyte activity, phagocyte function, leukocyte mobility, and possibly antibody and interferon.

# Vitamin B3:

Contributes to normal growth and development as well as the reduction of tiredness and fatique.

Functions as an antioxidant and protects cells against the damaging effects of free radicals

Plays an essential role in the maintenance of immune function. It is important for normal neutrophil, natural killer cell, and T-lymphocyte function within the immune system. Zinc acts by decreasing levels of the suppressor T cells and increasing the ratio of helper to suppressor cells.

# Vitamin B5:

Contributes to tissue formation and the reduction of tiredness and fatigue. Pantothenic acid (Vitamin B5) serves as precursor of coenzyme A (CoA), which is required for the release of energy from carbohydrates; in the synthesis and degradation of fatty acids; and in the synthesis of sterols, steroid hormones and other compounds.

# Vitamin B6:

Vitamin B6 contributes to the normal function of the nervous system and energy-yielding metabolism. Also supports normal functioning of the immune system as it is required for antibody production. Vitamin B6 increases the number of T lymphocyte, T helper, and T suppressor cells.

Helps to metabolise carbohydrates, fats and proteins, and therefore supports the reduction of tiredness and fatigue. Also contributes to tissue formation and the protection of cells from oxidative stress.

Helps to metabolise carbohydrates, fats and proteins, and therefore supports energy-yielding metabolism. Also contributes to normal functioning of the nervous system

Contributes to the maintenance of eyesight, skin, membranes and is essential for healthy immune function. Retinoic acid, a metabolite of vitamin A, is required in maintaining sufficient levels of natural killer cells, and may increase the production of cytokines, such as interleukin 1. Additionally, B lymphocyte growth, differentiation, and activation, are dependent on retinol.

### Folic acid:

Supports the formation of red blood cells and is an important factor in the maintenance of good health.

Serves as an antioxidant and protects cells from the damage caused by free radicals. Selenium improves immune function by increasing the activity of interleukin-2 and promoting the normal growth and development of T helper

Helps to metabolise carbohydrates, fats and proteins, and therefore supports energy-yielding metabolism. Also contributes to normal psychological function and a healthy nervous system. Biotin deficiency is associated with reduced antibody synthesis which may lead to immune deficiency.

### Vitamin D:

Plays an essential role in maintaining strong bones by supporting the absorption and use of calcium and phosphorous. It also contributes to the normal function of the immune system.

### Vitamin B12:

Plays an important role in red blood cell formation and contributes to normal homocysteine metabolism. Vitamin B12 also supports healthy immune function.

### Beta-1.3/1.6 Glucan:

Yeast derived (Saccharomyces cerevisiae) beta-1,3/1,6 glucan acts as an oral immune activator through its effect on macrophage immune cells. It binds to monocyte and macrophage cells, increase the proliferation and activation of macrophages, and increase the production of cytokine interleukin-1 by macrophages, which promotes the release of interleukin-2 by T-cells. Beta-1,3/1,6 glucan also has powerful antioxidant properties and acts as free-radical scavenger which enables the immune system to fight back against health invaders such as fungus, bacteria, viruses and parasites.

### INDICATIONS:

CAMED Immune Defense consists out of a combination of vitamins and minerals, combined with Beta-1,3/1,6 glucan which promotes healthy immune function and supports the maintenance of good health.

# CONTRAINDICATIONS:

CAMED Immune Defense is contraindicated in:

Patients with a hypersensitivity to any of the ingredients contained in CAMED Immune Defense (see "COMPOSITION").

# WARNINGS AND SPECIAL PRECAUTIONS:

CAMED Immune Defense should be used with caution in: Patients with a history of developing renal calculi Patients suffering from gastrointestinal sensitivity (see "SIDE EFFECTS").

Some of the ingredients contained in CAMED Immune Defense may interact with the following medicines. Caution is advised:

Using vitamin A with retinoids, such as isotretinoin and tretinoin, may contribute to hypervitaminosis A.

# Antibiotics:

Using zinc with fluoroquinolones and tetracyclines can reduce the absorption thereof. Advise patients to take these antibiotics 2 to 3 hours before or after CAMED Immune Defense.

# Antiepileptics:

Using folic acid with phenytoin may lead to reduced levels of serum-phenytoin concentrations. Folic acid may also reduce the levels of primidone when used

Using folic acid and/or vitamin B6 with phenobarbital may lead to reduced levels of serum-phenobarbital concentrations.

# Anti-Parkinson Agents:

Using vitamin B6 with levodopa may lead to reduced serum levels of levodopa. This can be prevented by co-administering a dopa-decarboxylase inhibitor.

# **HUMAN REPRODUCTION:**

The safety and efficacy of CAMED Immune Defense in pregnancy and lactation has not been established.

# DOSAGE AND DIRECTIONS FOR USE:

Adults: Take 2 capsules once daily with or just after a meal.

## SIDE EFFECTS:

Immune system disorders: Less frequent: Hypersensitivity reactions

# Gastrointestinal disorders:

Frequent: gastrointestinal disturbances which may include abdominal pain, dyspepsia, nausea, diarrhoea and gastrointestinal irritation.

# Skin and subcutaneous tissue disorders:

Frequency unknown: Skin reactions.

# KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

Excessive doses of CAMED Immune Defense may increase the risk of experiencing side effects (see "SIDE EFFECTS"). Symptomatic treatment is suggested in the case of overdose.

# IDENTIFICATION:

An amethyst and pink coloured, hard gelatine 2-part capsule.

# PRESENTATION:

A unit carton containing 60 blistered CAMED Immune Defense capsules.

# STORAGE INSTRUCTIONS:

Store at or below 25 °C in a dry place. Protect from light. KEEP OUT OF REACH OF CHILDREN.

# APPLICATION NUMBER

NAPPI Code: CAMED Immune Defense (60 Capsules) 3002756001

# NAME AND ADDRESS OF THE APPLICANT

CAMED Pharmaceuticals (Pty) Ltd P O Box 784 Lephalale Limpopo 0555

# DATE OF PUBLICATION

September 2020

## **COMPLEMENTARY MEDICINE**

Health supplement

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

Professional information is electronically available at <a href="www.camed-pharma.com">www.camed-pharma.com</a>

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