

## Proposed professional information for IMMUNE BOOST CBD capsules

### COMPLEMENTARY MEDICINE:

### COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

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

### SCHEDULING STATUS

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#### 1 NAME OF THE MEDICINE

IMMUNE BOOST CBD capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

*Echinacea purpurea* (L.) Moench 110 mg

[flowering tops, 30:1 extract standardised to 4 % chicoric acid, providing 3,3 g dried herb equivalent]

*Sambucus williamsii* Hance (black elderberry) 105 mg

[fruit, 30:1 extract standardised to 25 % anthocyanidins, providing 3,15 g dried herb equivalent]

Ascorbic acid (vitamin C) 65 mg

Resveratrol 60 mg

Tocopherol (vitamin E) 25 mg

*Olea europaea* L. (olive leaf) 12,5 mg

[leaf, 85:1 extract standardised to 20 % hydroxytyrosol, providing 1,06 g dried herb equivalent]

Zinc 12,5 mg

Pyridoxine (vitamin B6) 7,5 mg

*Cannabis sativa* L. (CBD isolate) 5 mg

[hemp leaves and flowers, standardised to 99,9 % cannabidiol isolate]

Cyanocobalamin (vitamin B12) 25 µg

Cholecalciferol (vitamin D3) 10 µg

Sugar free.

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Capsules.

Clear hypromellose capsules containing a beige coloured powder.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

IMMUNE BOOST CBD may assist in boosting your immune system, supporting the body's defence against viral infections and general maintenance of good health.

#### **4.2 Posology and method of administration**

Take two capsules in the morning with water and food.

Do not exceed the maximum daily dose of four capsules.

#### **4.3 Contraindications**

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

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

##### **Bleeding disorders:**

IMMUNE BOOST CBD may have antiplatelet effects and may increase the risk of bleeding when used in patients with bleeding disorders. Patients should be advised to discontinue IMMUNE BOOST CBD at least 2 weeks prior to surgical procedures (see section 4.5).

**Diabetes mellitus:**

IMMUNE BOOST CBD may increase insulin levels and/or decrease blood glucose levels and cause hypoglycaemia. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5).

**Autoimmune diseases and immunodeficiencies:**

IMMUNE BOOST CBD may exacerbate autoimmune diseases by stimulating the disease activity. Patients with autoimmune diseases including multiple sclerosis, systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA) should avoid or use IMMUNE BOOST CBD with caution.

**4.5 Interaction with other medicines and other forms of interaction****CNS depressants:**

IMMUNE BOOST CBD can have CNS depressant effects which might be enhanced by concomitant use with medicines and herbal supplements with sedative properties.

**Anticoagulant/antiplatelet medicines:**

IMMUNE BOOST CBD may reduce platelet aggregation and may enhance the effects of anticoagulant/antiplatelet medicines including aspirin, clopidogrel, heparin, warfarin, or herbal supplements, such as garlic, ginger and ginkgo. Concomitant use may increase the risk of bleeding and caution is advised (see section 4.4).

**Antidiabetic medicines:**

Concomitant use of IMMUNE BOOST CBD with antidiabetic medicines including glimepiride, metformin, insulin, or herbal supplements such as ginger, ginseng and garlic may have an additive effect with antidiabetic medicine and cause hypoglycaemia (see section 4.4).

**Immunosuppressant medicine:**

IMMUNE BOOST CBD has immune system stimulating properties and may interfere with immunosuppressant medicine including azathioprine, ciclosporin and tacrolimus.

**Cytochrome P450 substrates:**

IMMUNE BOOST CBD may increase the levels of medicines that are metabolised by CYP3A4 and increase their effects and adverse effects. Medicines that may be affected include propranolol, losartan, diltiazem, nicardipine, verapamil, ketoconazole and itraconazole.

**4.6 Fertility, pregnancy and lactation**

Safety in pregnancy and lactation has not been established. IMMUNE BOOST CBD should not be taken during pregnancy or lactation.

**4.7 Effects on ability to drive and use machines**

IMMUNE BOOST CBD may cause side effects such as drowsiness and can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery until the effects of IMMUNE BOOST CBD are known.

**4.8 Undesirable effects**

IMMUNE BOOST CBD are generally well tolerated.

**Psychiatric disorders:**

*Frequent:* drowsiness.

**Gastrointestinal disorders:**

*Frequent:* nausea, vomiting, diarrhoea, gastrointestinal irritation.

**Skin and subcutaneous tissue disorders:**

*Frequent:* skin rash.

## **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<http://www.sahpra.org.za/Publications/Index/8>

## **4.9 Overdose**

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### ***Category and class:***

D 33.7 Combination Product

IMMUNE BOOST CBD is a multivitamin and mineral supplement with added herbal components which assist in boosting the immune system, supporting the body’s defence against viral infections and for general maintenance of good health.

### **5.2 Pharmacokinetic properties**

The oral bioavailability of *Echinacea purpurea* is variable based on the preparation used and has shown a half-life of about 1,3 hours.

Peak plasma concentration of the anthocyanidins from *Sambucus williamsii* are reached within 3 to 4 hours and are eliminated through urine.

Vitamin C is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.

Peak plasma levels of resveratrol are reached within 0,5 to 1,5 hours and 77 % of urinary resveratrol and metabolites are excreted within 4 hours of ingestion of 5 grams.

Vitamin E is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.

Conjugated hydroxytyrosol from *Olea europaea* reaches peak plasma concentrations after 64 – 80 minutes with a clearance by 240 minutes in the urine.

Zinc is a biologically essential trace element that is absorbed in the small intestines and is distributed in the body in skeletal muscle and bone. It is mainly excreted through the faeces.

Vitamin B6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Cannabidiol (CBD) from *Cannabis sativa* L. is poorly absorbed after oral administration. CBD and its metabolites have a half-life of about 58 hours and is primarily excreted in the faeces, with minimal renal elimination.

Vitamin B12 is an essential water-soluble vitamin. It is absorbed in the terminal ileum and is mainly stored in the liver. Vitamin D is excreted via urine, faeces and bile.

Vitamin D is a fat-soluble vitamin. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol. Excretion occurs mainly through the bile and faeces, with small amounts appearing in urine.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Hypromellose.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

24 months.

### **6.4 Special precautions for storage**

Store at or below 25 °C in a dry place protected from light.

Keep the container in the outer carton.

Keep the container tightly closed.

#### **6.5 Nature and contents of container**

Amber glass container with a black polypropylene cap.

Pack size: 60 capsules.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Baltimore (Pty) Ltd

Foregate Square 1A

Heerengracht

Foreshore

Cape Town

8001

### **8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

### **9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

### **10. DATE OF REVISION OF THE TEXT**

This leaflet was last revised in July 2020.