

## Proposed professional information for MOOD 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

MOOD CBD capsules

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

*Passiflora caerulea* L. (passion flower) 150 mg

[Whole plant, 10:1 extract, providing 1,5 g dried herb equivalent]

*Bacopa monnieri* (L.) Wettst. 100 mg

[Whole plant, 30:1 extract standardised to 50 % bacopasides, providing 3 g dried herb equivalent]

*Griffonia simplicifolia* (DC.) Baill. (5-HTP) 100 mg

[Seeds, 14:1 extract standardised to 99 % 5-hydroxytryptophan, providing 1,4 g dried herb equivalent]

L-theanine 30 mg

*Sceletium tortuosum* (L.) N.E. Br. 20 mg

[Dried stems and leaves]

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

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

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**

MOOD CBD may assist in improving your mood while decreasing anxiety, stress, depression and mood swings.

MOOD CBD may also assist in regulating heart rhythm and lowering high blood pressure.

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

Take two capsules in the morning with water and food. If necessary, take an extra two capsules as a booster in the afternoon or evening.

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**

#### **Surgery:**

MOOD CBD has central nervous system (CNS) depressant effects which might cause additive CNS depression when combined with anaesthesia. Discontinue use at least 2 weeks prior to surgical procedures (see section 4.5).

#### **4.5 Interaction with other medicines and other forms of interaction**

##### **CNS depressants:**

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

##### **Antidepressants:**

Combining MOOD CBD with antidepressants might increase the risk of serotonergic effects including serotonin syndrome and cerebral vasoconstrictive disorders. Serotonergic antidepressants include fluoxetine, paroxetine, sertraline and herbal supplements such as St. John's wort.

##### **Cytochrome P450 substrates:**

MOOD 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, nifedipine, verapamil, ketoconazole and itraconazole.

#### **4.6 Fertility, pregnancy and lactation**

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

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

MOOD 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 MOOD CBD are known.

#### **4.8 Undesirable effects**

MOOD CBD is 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

MOOD CBD is a supplement containing CBD, various herbal components and an amino acid, L-theanine, which may assist in improving your mood while decreasing anxiety, stress, depression and mood swings. MOOD CBD may also assist in regulating heart rhythm and lowering high blood pressure.

## **5.2 Pharmacokinetic properties**

There is insufficient information available about the pharmacokinetic properties of *Passiflora caerulea* L., *Bacopa monnieri* (L.) Wettst., *Griffonia simplicifolia* (DC.) Baill. and *Sceletium tortuosum* (L.).

L-theanine is absorbed through the intestines, distributed to the plasma and erythrocytes, hydrolysed to ethylamine and glutamic acid, 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 are primarily excreted in the faeces, with minimal renal elimination.

## **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.