**Proposed professional information for MIND 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

MIND CBD capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

| | |
|---|---|
| *Gingko biloba* L. | 110 mg |
| [Leaves, 50:1 extract, providing 5,5 g dried herb equivalent] | |
| *Panax ginseng* C.A. Mey. | 80 mg |
| [Stems and leaves, 20:1 extract standardised to 80 % ginsenosides, providing 1,6 g dried herb equivalent] | |
| *Rhodiola rosea* L. | 62,5 mg |
| [Flowers, 5:1 extract standardised to 3 % salidroside, providing 312,5 mg dried herb equivalent] | |
| L-theanine | 52,5 mg |
| Phosphatidylserine | 42,5 mg |
| L-alpha-glycerylphosphorylcholine (alpha GPC) | 40 mg |
| *Coleus forskohlii* (Willd.) Briq (forskolin) | 11,5 mg |
| [Roots, 15:1 extract standardised to 20 % forskolin, providing 172,5 mg dried herb | |

equivalent]

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

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

Pyridoxine (vitamin B6) 1 mg

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

MIND CBD may assist in improving memory, focus and brain clarity by supporting cognitive health and brain function.

### 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

**Bleeding disorders:**

MIND 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 MIND CBD at least 2 weeks prior to surgical procedures (see section 4.5).

**Diabetes mellitus:**

MIND 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).

**Hypotension:**

MIND CBD may reduce blood pressure. Caution is advised with patients suffering from low blood pressure and/or patients taking medicines for hypertension (see section 4.5).

**Epilepsy:**

MIND CBD can cause seizures. Caution is advised for patients with epilepsy and/or taking medicines for epilepsy (see section 4.5).

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

**CNS depressants:**

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

**Anticoagulant/antiplatelet medicines:**

MIND 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 MIND 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).

**Antihypertensive medicines:**

MIND CBD may decrease blood pressure. Concomitant use with antihypertensive medicines including captopril, enalapril, losartan, valsartan and amlodipine, or herbal supplements such as coenzyme Q-10 and fish oil, may increase the risk of hypotension (see section 4.4).

**Anticonvulsant medicines:**

Caution is advised for patients taking medicines for epilepsy as MIND CBD can cause seizures (see section 4.4).

**Cytochrome P450 substrates:**

MIND 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. MIND CBD should not be taken during pregnancy or lactation.

## 4.7 Effects on ability to drive and use machines

MIND CBD may cause side effects such as dizziness 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 MIND CBD are known.

## 4.8 Undesirable effects

MIND CBD is generally well tolerated.

**Psychiatric disorders:**

*Frequent:* insomnia.

**Nervous system disorders:**

*Frequent:* dizziness, headache.

**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

MIND CBD is a supplement containing CBD, various herbal components and vitamins, which may assist in improving memory, focus and brain clarity by supporting cognitive health and brain function.

### 5.2 Pharmacokinetic properties

Ginkgolide A, ginkgolide B and bilobalide concentrations are found in the body after administration of ginkgo extracts, with half-lives of 4, 6 and 3 hours, respectively. The amounts of each excreted unchanged in the urine were approximately 70 %, 50 % and 30 %, respectively.
After oral administration of ginseng, compound K is absorbed into the blood over 24 hours.
The bioavailability of salidroside, a constituent of *Rhodiola rosea* L., is about 32,1 % with a half-life of around 2 hours.
L-theanine is absorbed through the intestines, distributed to the plasma and erythrocytes, hydrolysed to ethylamine and glutamic acid, and excreted in the urine.
Phosphatidylserine are found in the blood within 30 minutes of oral intake. During digestion, fatty acids are removed by lipases in the small intestine. Phosphatidylserine accumulates in the brain and liver after oral intake.
Alpha GPC is rapidly metabolised by glycerolphosphorylcholine diesterase to form glycerophosphate and choline.
The coleus constituent, forskolin, is minimally soluble in water and bioavailability is poor after oral administration.
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.
Vitamin B6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the 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.