Professional Information

Complementary Medicine

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

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

CBD Rooibos SLEEP
Rooibos & Chamomile + CBD

Strength
Multicomponent

Pharmaceutical form
Teabag

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each teabag contains:

Aspalathus linearis (Rooibos) [Fermented cut leaves and twigs]	1,4 g
Matricaria recutita L. (Chamomile) [Dried and cut flowers]	0,6 g
Cannabis sativa (Cannabidiol) [Leaves, oil extract]	11,2 mg
providing Cannabidiol (approximate quantity after brewing)	2,0 mg

For full list of excipients, see section 6.1

Sugar Free

3. PHARMACEUTICAL FORM

Square (65 mm x 65 mm) teabag made of patterned filter paper containing brown tea leaves.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

A discipline-specific combination medicine that contributes to nervous system health, healthy sleep, and is an antioxidant.

4.2. Posology and method of administration

Posology

Serving size for adults (18+) is 1 teabag per day or at the discretion of your health care provider (adult's daily intake of CBD should not exceed 20 mg).
Add boiling water to teabag in a cup, brew for 4-5 minutes and drink orally.

Do not use longer than 3 months without advice from a relevant health care provider.

Paediatric population

Not be taken by children under 18 years of age.

Method of administration

For oral use

4.3. Contraindications

- Hypersensitivity to the active substances or to any of the excipients or residues from the manufacturing process, as well as any contraindication arising from the presence of certain excipients.
- Not to be used during pregnancy or breastfeeding.
- Not be taken by children under 18 years of age.

4.4. Special warnings and precautions for use

- If symptoms persist or get worse, consult a relevant health care provider for advice.
- Oral preparations of cannabidiol (CBD) taken at doses more than 20 mg per day may worsen symptoms of Parkinson's disease.
- The use of CBD together with opioids and caffeine should be avoided.
- Taking CBD may cause light-headedness, dry mouth or drowsiness. (See section 4.7)

4.5. Interaction with other medicines and other forms of interaction

CBD may interact with numerous medicines.

- Taking CBD may (theoretically) cause additive effects when taking sedatives or anaesthetics enhancing the effect of the sedatives beyond what is intended.
- CBD inhibits Cytochrome P450 (CYP) system in vitro. The effect of CBD in humans has not been fully established.
- Co-administration of CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir or clarithromycin) or inducers (e.g., rifampicin, carbamazepine, phenytoin, phenobarbital or St. John's wort) may affect medication levels.
- Avoid use of CBD with clobazam, stiripentol or valproate.

4.6. Fertility, pregnancy and lactation

Not to be used during pregnancy or breastfeeding. (See section 4.3)

4.7. Effects on ability to drive and use machines

Taking CBD may cause light-headedness, dry mouth or drowsiness. Do not drive or operate machinery until you know how CBD affects you. (See section 4.4)

4.8. Undesirable effects

Adverse reactions are listed below by system organ class and by frequency. Frequencies are defined as: Very common (≥1/10), common (≥ 1/100, < 1/10), uncommon (≥1/1,000, < 1/100), rare (≥1/10,000, < 1/1,000), very rare (< 1/10,000), frequency not known (cannot be estimated from the available data), according to the MedDRA frequency convention and system organ classification.

MedDRA System Organ Class	Frequency	Adverse Reaction
Immune system disorders	Frequency not known	Hypersensitivity reaction (such as rash)
Nervous system disorders	Frequency not known	Light-headedness, dry mouth, or drowsiness.

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. Health care 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: https://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

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Discipline-specific Combination product

The Pharmacological action of CBD Rooibos SLEEP / Rooibos & Chamomile + CBD is achieved by the combination of ingredients which contribute to nervous system health, healthy sleep, and act as an antioxidant.

5.2. Pharmacokinetic properties.

No pharmacokinetic information available.

5.3. Preclinical safety data

No preclinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Medium-chain triglycerides (MCT) Oil

6.2. Incompatibilities

No information available

6.3. Shelf life

18 months

6.4. Special precautions for storage

Once opened, store in an airtight container in a cool, dry place, at or below 25 °C.

6.5. Nature and contents of container

Display carton with 20 teabags packed in a sealed silver foil pouch.

6.6. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MC Pharma (Pty) Ltd
62 Constantia Avenue
Mnandi
Centurion
0157

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

January 2023

10. DATE OF THE REVISION OF TEXT