

Proposed professional information for SLEEP 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

S0

1 NAME OF THE MEDICINE

SLEEP CBD capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Valeriana officinalis L. 120 mg

[Roots, 15:1 extract standardised to 0,8 % valeric acid, providing 1,8 g dried herb equivalent]

Withania somnifera (Ashwagandha) 110 mg

[Roots, 35:1 extract standardised to 7 % withanolide, providing 3,85 g dried herb equivalent]

Magnesium citrate 60 mg

Providing magnesium (elemental) 6,84 mg

Sceletium tortuosum (L.) N.E. Br. (Canna) 50 mg

[Dried stems and leaves]

Humulus lupulus L. (Hops) 40 mg

[Flowers, 20:1 extract standardised to 20 % flavones, providing 800 mg dried herb equivalent]

Cannabis sativa L. (CBD isolate) 20 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

SLEEP CBD may assist the patient to fall asleep faster and to obtain an improved and deeper natural sleeping pattern.

4.2 Posology and method of administration

Take one capsule with water in the evening at least 30 minutes before you go to sleep.

Do not exceed the maximum daily dose of one capsule.

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:

SLEEP 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:

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

Cytochrome P450 substrates:

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

4.7 Effects on ability to drive and use machines

SLEEP 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 SLEEP CBD are known.

4.8 Undesirable effects

SLEEP CBD is generally well tolerated.

Psychiatric disorders:

Frequent: drowsiness.

Gastrointestinal disorders:

Frequent: nausea, vomiting, diarrhoea, gastrointestinal irritation.

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

SLEEP CBD is a supplement containing CBD, various herbal components and magnesium which may assist the patient to fall asleep faster and to obtain an improved and deeper natural sleeping pattern.

5.2 Pharmacokinetic properties

There is insufficient information available about the pharmacokinetic properties of *Withania somnifera* and *Sceletium tortuosum* (L.).

Maximum valeric acid serum concentrations from *Valeriana officinalis* L. occur within 1 – 2 hours.

The half-life of valeric acid is about 1,1 hours.

Magnesium is absorbed through the gastrointestinal tract, distributed evenly between the skeleton and soft tissue, and primarily excreted via the kidneys.

After oral administration, the *Humulus lupulus* L. (hops) constituents xanthohumol, isoxanthohumol and 8-prenylnaringenin appear to be distributed to glandular tissue. These constituents primarily undergo phase II metabolism and partially undergo phase I metabolism. 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.