

Professional information for CBD Dreams 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

CBD Dreams Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule provides:

Matricaria chamomilla L. (Chamomile) 50 mg

[Flower, powder]

Withania somnifera (L.) Dunal (Ashwagandha) 50 mg

[Root, 4:1 extract standardised to 1,5% withanolides]

Cannabis sativa L. (CBD extract) 5 mg

[Hemp leaves and flowers, 0,64:1 extract standardized to 2,84 % cannabidiol providing 176 mg dried herb equivalent]

Thiamine hydrochloride 0,405 mg

providing thiamine (vitamin B1)

0,17 mg

Sugar free.

3. PHARMACEUTICAL FORM

Capsules.

Oblong, clear size 0 capsule filled with a white/beige powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Supports the psychological function.

4.2 Posology and method of administration

Take 1 capsule daily on an empty stomach or as prescribed by your healthcare provider.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or excipients (see sections 2 and 6.1).
- Not for use in persons under the age of 18 years.

4.4 Special warnings and precautions for use

- If you suffer from a chronic medical condition use this product under the supervision of your healthcare provider.
- Discontinue the use of this product where there is sensitivity towards any of the ingredients.

4.5 Interaction with other medicines and other forms of interaction

If you are taking chronic prescription medication, consult your healthcare provider before using CBD Dreams.

4.6 Fertility, pregnancy and lactation

Pregnant and breastfeeding women should avoid using CBD Dreams.

4.7 Effects on ability to drive and use machines

It is not known if CBD Dreams Capsules has an effect on the ability to drive or use machines. Caution is advised before driving a vehicle or operating machinery until the effects of CBD Dreams Capsules are known.

4.8 Undesirable effects

Discontinue the use of this product where there is sensitivity towards any of the ingredients.

Reporting of suspected adverse reactions:

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

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

4.9 Overdose

Use only as directed. Do not exceed the recommended dose.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product

The endocannabinoid system (ECS) is a biological system composed of endocannabinoids, which are endogenous lipid-based retrograde neurotransmitters that bind to cannabinoid receptors, and cannabinoid receptor proteins that are expressed throughout the vertebrate central nervous system (including the brain) and peripheral nervous system.

Cannabidiol (CBD), a phytocannabinoid is one of some 113 identified cannabinoids in hemp and accounts for up to 40 % of the plant's extract.

Vitamin B1 combines with ATP to form thiamine dophosphate, which is a coenzyme in carbohydrate metabolism.

Ashwagandha is said to have an "anti-stress" effect. It suppresses stress-induced increases of dopamine receptors and also reduces the stress-induced increases of plasma corticosterone.

Chamomile contains many active ingredients that are responsible for the sedative activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate

Hypromellose

Magnesium stearate

Silicon dioxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

6.5 Nature and contents of container

Cobalt blue glass labelled bottle in a printed outer carton containing 30 capsules

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Elixinol SA

Castle Mews

16a New Market Street

Foreshore

Cape Town

South Africa

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8. REGISTRATION NUMBER

To be allocated by SAHPRA.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated by SAHPRA.

10. DATE OF REVISION OF THE TEXT

November 2020.