

Professional information for CBD Digest 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 Digest Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule provides:

Calcium carbonate 169 mg

providing calcium (elemental) 67,6 mg

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]

Lactobacillus acidophilus 5 x 10⁶ cfu

Bifidobacterium bifidum 5 x 10⁶ cfu

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 digestive system.

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 Digest.

4.6 Fertility, pregnancy and lactation

Pregnant and breastfeeding women should avoid using CBD Digest.

4.7 Effects on ability to drive and use machines

It is not known if CBD Digest 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 Digest 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 Digest Capsules is important.

It allows continued monitoring of the benefit/risk balance of CBD Digest 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.

Lactobacillus refers to a group of lactic acid producing bacteria that are symbiotic and make up some of the normal flora in the human gastrointestinal and genitourinary tracts.

Bifidobacteria normally colonise the human colon and provide a microbial barrier to infection.

Calcium is a mineral that contributes to the maintenance of good health.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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 Newmarket Street

Foreshore

Cape Town

South Africa

www.elixinol.co.za

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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.