

Professional information for CBD Turmeric 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 Turmeric Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule provides:

<i>Curcuma longa</i> L. (Turmeric)	200 mg
[root, 25:1 extract, standardised to 95 % curcuminoids providing 190 mg dried herb equivalent]	
<i>Cannabis sativa</i> L. (CBD extract)	5 mg
[hemp leaves and flowers, 0,64:1 extract standardised to 2,84 % cannabidiol providing 176 mg dried herb equivalent]	
Ascorbic acid (vitamin C)	15 mg
Bioperine® (Black pepper extract)	5,25 mg
Manganese sulphate	1,51 mg
providing manganese (elemental)	0,5 mg

Sugar free.

3. PHARMACEUTICAL FORM

Capsules.

Oblong, clear size 0 capsule filled with a orange/yellow powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Supports collagen formation.

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 Turmeric.

4.6 Fertility, pregnancy and lactation

Pregnant and breastfeeding women should avoid using CBD Turmeric.

4.7 Effects on ability to drive and use machines

It is not known if CBD Turmeric 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 Turmeric 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 Turmeric Capsules is important. It allows continued monitoring of the benefit/risk balance of CBD Turmeric 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.

Turmeric contains curcuminoids which have anti-inflammatory properties possibly by inhibiting cyclooxygenase-2, prostaglandins and leukotrienes.

Vitamin C is a water soluble vitamin found in fresh fruits and vegetables. Vitamin C has a role in several physiological functions. Vitamin C is also involved in a variety of metabolic processes including oxidation-reduction reactions and cellular respiration, carbohydrate metabolism, synthesis of lipids and proteins, catabolism of cholesterol to bile acids, conversion of folic acid to folinic acid, and iron metabolism. Vitamin C is probably best known for its effects as an antioxidant and its role in maintaining proper immune function.

Manganese is a trace mineral that acts as a cofactor in several metabolic and enzymatic reactions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose

Magnesium stearate

Microcrystalline cellulose

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

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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.