FORMULÆ

THE ART & SCIENCE OF COMPOUNDING

CBD OIL

Cannabidiol 120mg/mL oil solution.

ACTIVE INGREDIENT / STORAGE

Our first full spectrum formula, CBD Olive Oil Tincture is crafted using four premium ingredients with both safety and efficacy in mind. This Certified Organic CBD oil tincture contains a 99.9% purity of CBD isolate that are phytonutrients including flavonoids, terpenes, cannabinoids that work together synergistically to promote wellness and balance throughout the body and mind.

STORAGE CONDITIONS

120mg/mL oily solution supplied in a 20ml / 30ml amber bottle with a child-resistant lid. Store below 25°C in a dry place. Keep out of reach of child

WHAT IS IN THIS LEAFLET

This leaflet contains information about your medication. All medicines are associated with some risks, however your doctor/pharmacist has weighed those against the benefits of you taking the medication and the positive effects they expect to see. Should you have any concerns, please contact us for more information. Make sure you keep this leaflet close to your medicine as you may need to refer to it again in the future.

PRODUCT DESCRIPTION

Cannabidiol (CBD) is a major, non-psychoactive constituent of Cannabis sativa and the active drug ingredient in Compounded Cannabidiol Oral Oil Solution. It is a colourless to light yellow powder or crystals, is insoluble in water and formulated into various strengths and forms for flexibility of administration.

Terpenes are constituents of the essential oils of the Cannabis sativa plant and provide the flavour and fragrance to the compounded formulations. It is also reported to enhance the activity of the major cannabinoids in cannabis when used in conjunction.

Solution for oral administration:

Each millilitre of solution contains 120mg cannabidiol and a proprietary Olive Oil blend.

Inactive ingredients: Olive Oil.

Sugar and alcohol free.

MOLECULAR FORMULA

$C_{21}H_{30}O_2$

Molecular weight: 314.464g/mol

CLINICAL PHARMACOLOGY

The endocannabinoid system includes two primary types of receptors that bind to cannabinoids: CB1 and CB2. CBD does not fit into either type of receptor perfectly. Instead, it stimulates activity in both resulting in changes within cells that contain either receptor. Because CB1 and CB2 receptors are present throughout the body, the effects of CBD are systemic.

When introduced into the endocannabinoid system, CBD causes an increased release of 2-AG, one of the endogenous cannabinoids. Like CBD, 2-AG stimulates activity at both CB1 and CB2 receptors thus enhancing its overall effects. CBD also inhibits the activity of fatty acid amide hydroxylase or FAAH. This slows the deterioration of anandamide, another important endogenous cannabinoid found naturally within the body. CBD has analgesic, anticonvulsant, muscle relaxant, anxiolytic, neuroprotective, anti-oxidant and anti-psychotic activity.

CBD is a lipophilic molecule and following oral administration, is rapidly distributed

into fatty tissues. Additionally, some of the CBD undergoes hepatic first-pass metabolism to its primary metabolite, 7-OH-CBD. Protein binding of CBD is high (~97%) and it may be stored for as long as four weeks in the fatty tissues from which it is slowly released at sub-therapeutic levels back into the bloodstream, then metabolised and excreted via the urine and faeces.

CBD is metabolised in the liver and approximately one third of the parent drug and their metabolites are excreted in the urine (the remainder via the faeces). The metabolism of CBD is extensive through the cytochrome P450 enzyme system with more than 33 metabolites identified in urine.

After oral administration, CBD has an onset of action of approximately 0.5 to 1 hours, and peak effects at 2 to 4 hours. Multiple daily doses maybe required for maximal effect.

Elimination of oral CBD is bi-phasic with an initial half life of approximately four hours and a terminal elimination half-life of ~ 18 to 32 hours or longer. Cannabinoids including CBD are distributed throughout the body due to their high lipid solubility and therefore, accumulate in fatty tissue. The release of cannabinoids from fatty tissue is responsible for the prolonged terminal elimination half-life.

INDICATIONS AND USAGE

CBD preparations have been documented and observed to assist with:

- Management of treatment-resistant seizures related to paediatric-onset epilepsy
- Chronic inflammation and pain
- Symptom management in palliative care
- Anxiety, mood and sleep disturbances

CONTRADICTIONS

CBD preparations are contraindicated in patients with a known sensitivity to cannabidiol or any of its other ingredients. It contains cannabidiol, Olive Oil

PRECAUTIONS

Individual response to CBD and cannabinoid medicines varies widely and patients being considered for treatment with these medicines should be assessed by their prescribing doctors and reassessed after four weeks of treatment.

WARNINGS

DRIVING AND OPERATING MACHINERY

Patients receiving treatment with CBD preparations should be appropriately advised about their ability to drive, operate machinery, or engage in any hazardous activity by their prescribing practitioner until it is established that they are able to tolerate the drug and perform such tasks safely.

PREGNANCY AND LACTATION

CBD is a Pregnancy Category C drug which means there are no adequate and well-controlled studies in pregnant women. CBD should be used only if the potential benefit justifies any potential risk to the foetus.

USE IN THE ELDERLY

There is limited data available on the use of CBD in elderly patients, therefore, the drug should be prescribed cautiously and carefully monitored in this patient population.

PATIENTS WITH SEVERE HEPATIC OR RENAL IMPAIRMENT

The effects of CBD in these patients may be exaggerated or prolonged. Frequent clinical evaluation by a clinician is recommended in these patient populations.

POTENTIAL ADVERSE REACTIONS

A safety review in 2011 on CBD demonstrated no significant side effects though it was noted that further studies are required. CBD is possibly safe when used appropriately and as directed.

Although rare, some reported side effects of CBD include drowsiness, dry mouth, vomiting, diarrhoea, fatigue and dizziness. CBD doses of up to 300mg daily have been used safely for up to 6 months. Higher doses of 1200-1500mg daily have been used safely for up to 4 weeks

DRUG INTERACTIONS

There may be a potential risk of drug-drug interactions due to the metabolism through the cytochrome P450 enzyme pathway.

CBD concentrations increase with CYP3A4 and CYP2C19 inhibitors (i.e. Azole antifungals, macrolide antibiotics, verapamil/diltiazem, omeprazole, fluoxetine etc).

CBD concentrations decrease with CYP3A4 and CYP2C19 inducers (i.e. St John's Wort, carbamazepine etc) CBD with sodium valproate increases liver enzymes. CBD with clobazam increases clobazam metabolites.

DOSAGE AND ADMINISTRATION

TITRATION

A titration period is required to reach optimal dose. The number and timing of administration will vary between patients. Doses may commence at 20mg daily (0.2ml) and increase every second or third day if relief is not achieved up to a maximum dose of 500mg daily 25ml . The optimal dose is the lowest dose that achieves the highest benefit.

ADULTS

Determining the optimal individualised dose of CBD may take some weeks, and side effects from either over- or under-dosing may cause temporary problems. If possible, the selected dosage should be maintained for a period of two weeks unless adverse effects such as fatigue are significant. Dosage reduction may be required in such circumstances.

CHILDREN

Dosage administration of CBD in children or adolescents below 18 years of age must be supervised by a doctor with expertise in the treatment of their symptoms or condition.

PHARMACY CONTACT

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