PRODUCT INFORMATION

CDA CBD 100-OIL

UPDATED: [12/05/2020] VERSION 1.0

CANNABIS DOCTORS
AOTEAROA

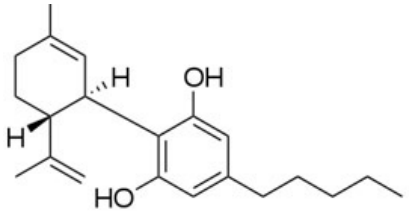
ANZPHARMA

CDA CBD 100-OIL

IMPORTANT: CDA CBD 100-OIL is provided via section 29 of the Medicine Act (1981) and only available with prescription from a doctor or vet.

I: NAME:

CDA CBD 100-OIL
Active ingredients: cannabidiol (CBD).
Each 30 mL of CDA CBD 100-OIL liquid contains:
3000 mg of cannabidiol from cannabidiol extracts of the cannabis sativa plant mixed into cold pressed hemp seed oil to 30mL. Each millilitre (mL) contains 100mg of cannabidiol (CBD).
Extraction Solvent: Cold Ethanol
Chemical structure of cannabidiol (CBD):



Molecular formula: C21H30O2
Molecular weight: 314.464g/mol
CAS Number: 13956-29-1
(Cannabidiol (CBD) Critical Review Report, 2018, p. 7)

II: DESCRIPTION:

CDA CBD 100-OIL is derived and extracted from the cannabis sativa plant, specifically bred to produce high CBD chemotypes.
The ingredients of CBD CDA 100-OIL are extracted through a high-grade cold ethanol extraction process.
CDA CBD 100-OIL is a yellow to golden colour in appearance with a characteristic odour of hemp (due to the hemp seed oil carrier oil). It is water insoluble and supplied as decarboxylated (activated) oil, meaning it is ready to use with no further heating application required.
CDA-CBD 100-OIL is supplied in an amber coloured, light proof 30 mL medical grade glass bottle with a 1 mL oral dropper syringe. The bottle has a tamper-evident seal.

III: PHARMACOLOGY:

Pharmacotherapeutic group: Other Analgesics and other Antipyretics
ATC Code: N02BG10
Name: Cannabinoids
This group comprises analgesics, which cannot be classified in the preceding groups.
(Whocc.no, 2019)
CBD Mechanism of Action:
The two main cannabinoid (CB) receptors in the human endocannabinoid system are known as cannabinoid Receptor Type 1 (CB1) and Cannabinoid Receptor Type 2 (CB2). CB1 is primarily located in the central nervous system with some expression in the peripheral tissues. CB2 receptors can be found in the periphery on the immune cells, in the gastrointestinal tract, at low densities in the central nervous system, and in the haematopoietic system. The direct mechanism of action of CBD is still unclear, however, studies have shown CBD may be a negative allosteric modulator of the CB1 receptor, thereby acting as a non-competitive antagonist of the actions of tetrahydrocannabinol (THC) and other CB1 agonists. Furthermore, CBD may also act as an allosteric modulator at the CB2 receptor. Additionally, CBD interacts with the endocannabinoid system through indirect mechanisms such as enhanced action of endogenous cannabinoid ligand anandamide. This results in blockade of anandamide reuptake and the inhibition of its enzymatic degradation. [5,9,43]. CBD has also shown to be responsible for modulating several non-endocannabinoid signalling systems, expanding its potential clinical effects.
(Randall, 2007), (Cannabidiol (CBD) Critical Review Report, 2018, p. 13)

Absorption:
Oral consumption of cannabinoids are generally absorbed slowly. The bioavailability of cannabis taken orally is generally low due to the first pass liver metabolism (6%). Absorption usually takes 30-90 minutes, with peak onset of effect occurring 2-4 hours after consumption. Effects from oral cannabis can last 4-24 hours.
(Cannabidiol (CBD) Critical Review Report, 2018, p. 12)

Distribution:
CBD is rapidly distributed into the tissues and may preferentially accumulate in adipose tissues due to its high lipophilicity.
(Cannabidiol (CBD) Critical Review Report, 2018, p. 12)

Metabolism:
CBD is extensively metabolised in the liver and involves the CYP450 pathway. The seven recombinant human CYP enzymes identified as capable of metabolising CBD are: CYP1A1, CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP3A4, and CYP3A5. The two main isoforms involved are CYP3A4 and CYP2C19
(Cannabidiol (CBD) Critical Review Report, 2018, p. 12)

Excretion:
After oral administration of CBD, it is broadly metabolised in the liver and elsewhere by the P450 system then excreted in the urine and faeces. The half-life of CBD is estimated to be 20-36 hours and studies have shown it may take up to 5 days for 80-90% of the dose to be eliminated from the body. (Millar et al., 2018), (Cannabidiol (CBD) Critical Review Report, 2018, p. 11).

IV: CLINICAL TRIALS

No clinical trial data of CDA CBD 100-OIL is currently available.

V: INDICATIONS

CDA CBD 100-OIL is is only available via section 29 of the Medicine Act (1981) on prescription, so there are no specific indications approved for the use of CDA CBD 100-OIL, however there is evidence that CBD may be a useful treatment for a number of medical conditions. CDA CBD 100-OIL should only be used to treat specific conditions and/or symptoms individual to the patient and authorised by a medicinal practitioner.

VI: CONTRAINDICATIONS:

CBD is generally well tolerated with a good safety profile, however, may be contraindicated in patients who have a sensitivity to cannabinoids or to the hemp oil excipient.

VII: PRECAUTIONS:

Patients who commence CDA CBD 100-OIL should be assessed by the prescribing doctor at least four weeks after treatment commences. Dry mouth, dizziness and nausea are possible side effects reported with the use of CBD. These most frequently occur in the first few weeks of treatment. The consumption of alcohol is not recommended when patients are treated with medicinal cannabis.

Effects on fertility:
No data specific to CDA CBD 100-OIL is currently available. At present there is insufficient evidence to establish safety of CDA CBD 100-OIL in effects on fertility.

Use in pregnancy:
No data specific to CDA CBD 100-OIL is currently available. At present there is insufficient evidence to establish safety of CDA CBD 100-OIL on use in pregnancy.

Use in lactation:
No data specific to CDA CBD 100-OIL is currently available. At present there is insufficient evidence to establish safety of CDA CBD 100-OIL on use while breastfeeding.

Paediatric Use:
No data specific to CDA CBD 100-OIL is currently available. CDA CBD 100-OIL should only be used in children and adolescents below the age of 18 under the discretion of a medical practitioner.

Geriatric Use:
No data specific to CDA CBD 100-OIL is currently available, however cannabis extracts with high levels of CBD have shown to be suitable and well tolerated for use in the elderly.

Abuse potential:
As CBD exhibits no psychoactive components, there is low potential for dependency or abuse.
(Cannabidiol (CBD) Critical Review Report, 2018, p. 5) , (Guang Li and Alsherbiny, 2019)

VIII: INTERACTIONS WITH OTHER MEDICATIONS:

Cannabidiol (CBD) is metabolised by the cytochrome P450 enzyme (CYP450) in the hepatic system. Studies in vitro have shown CBD to be a moderate inhibitor of multiple CYP450 enzymes. Consequently, CDA CBD 100 Oil likely interacts with drugs that metabolise, inhibit or induce cytochrome P450 (CYP450) enzymes. Medications that are metabolised via the cytochrome P450 pathway need to be monitored closely under the care of a medical practitioner.

Potential drug interactions between CBD and anti-epileptic drugs such as Clobazam, Rufinamide, Topiramate, Zonisamide, and Diazepam require further monitoring. CBD can also increase warfarin levels, therefore, exercising caution and requiring monitoring from a medical practitioner is recommended.
(Cannabidiol (CBD) Critical Review Report, 2018, p. 15), (Anon, 2019)

IX: Adverse Effects:
No data specific to CDA CBD 100-OIL is currently available. However, CBD oil may cause adverse effects and the extent may vary between individuals. Evidenced based research has shown adverse effects associated with medicinal cannabis to be early, transient and well tolerated. The common possible side effects reported with the use of CBD include dry mouth, diarrhoea and nausea.

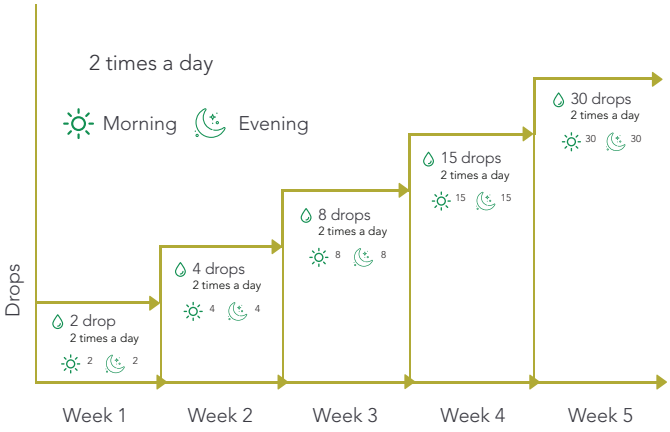
X: Dosage and Administration:
Dosing of CDA CBD 100-OIL is personalised based on each individual patient and the number and timing of drops/mL's to reach the optimal dose will vary between individuals. Determining the optimal individualised dose of CDA CBD 100-OIL may take some weeks to achieve. With CBD oil, it is important to start with a low dose and gradually increase the dose over a period of time (also known as titrate). CDA CBD 100-OIL is for oral - under the tongue (sublingual) consumption only.

The optimal dose is the lowest dose that achieves the highest benefit.

Recommended starting dose of CDA CBD 100-OIL:
2 drops (10mg): BD (Twice daily). Titrate as per table.

"Start Low and Go Slow"

CBD OIL DOSING TABLE



The table above can be used as a guide to assist patients in finding their dose.

Titrating Dose:

1. Increase drops/mL(s) as per titration guide. Do not exceed the maximum recommendation of 60 drops (300mg) per day.
2. Once desired symptom control has been achieved, the optimal maintenance dose has been found.

Maintenance Period:

Following titration period patients should maintain their optimal dose achieved during the titration period. Patients may spread their dose out during the day and titrate the dose up or down as appropriate. Continue with optimal dose until symptom control is no longer achieved or there is a change in condition, or presentation of adverse events.

Once effect of dose has worn off over time the patient can:

1. Consider increasing dose under the supervision of the prescribing practitioner.
2. Speak to their prescribing practitioner about dose changes.

Method of Administration:

CDA CBD 100-OIL is for oral consumption only. The bottle of CDA CBD 100-Oil includes rubber dropper.

Administration Technique:

Step 1. Start by eating something containing fat (i.e. avocado on toast, spoonful of yogurt, cheese)
Step 2. Twist the tamper-evident seal open. If the seal is broken contact your pharmacist or supplier immediately - Do not take the medication until advised.
Step 3. Insert the dropper into the bottle. Squeeze to fill the dropper and collect drops.
Step 4. Place drop/s on spoon to accurately measure dose.
Step 5. Slide drops off spoon to underneath the tongue.
Step 6. Swirl drops around the mouth for 90 seconds.
Step 7. Record dose.

XI: OVERDOSAGE:

There is no experience of deliberate overdose with CDA CBD 100-OIL. In case of overdose, contact your prescribing doctor for supportive and symptomatic care. For information on the management of overdose, contact the National Poison Centre on 0800 764 766 (New Zealand).

XII: PRESENTATION AND STORAGE CONDITIONS:

Presentation:

CDA CBD 100-OIL is supplied in an amber coloured, light proof 30 mL medical grade glass bottle with a 1 mL white oral dropper syringe. The bottle has a tamper-evident seal. There are approximately 20 drops per mL. CDA CBD 100-OIL is a yellow to dark golden colour in appearance with a characteristic odour of earth and hemp.

Pack size: 30 mL

Storage Conditions:

Store below 25° C. Store upright. Keep away from heat and direct sunlight. Keep out of reach of children.
Disposal: Return any expired or unused CDA CBD 100-OIL to a pharmacy for safe disposal.

XIII: NAME AND ADDRESS OF NZ DISTRIBUTOR:

ANZPHARMA

CDA CBD 100-OIL® Distrubuted in New Zealand by ANZ Pharma

707C Great South Road,
Penrose, Auckland
New Zealand
+6495712550
sales@anzpharma.co.nz
anzpharma.co.nz

XIV: POISON SCHEDULE OF THE MEDICINE:

Prescription only medicine

Bibliography

Guang Li, C. and Alsherbiny, M. (2019). Medicinal Cannabis—Potential Drug Interactions. [online] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6473892/ [Accessed 19 Jul. 2019].
Millar, S., Stone, N., Yates, A. and O'Sullivan, S. (2018). A Systematic Review on the Pharmacokinetics of Cannabidiol in Humans. Frontiers in Pharmacology, 9.
Randall, M. (2007). Endocannabinoids and the haematological system. [online] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2190025/ [AcWho. int. (2018). Expert Committee on Drug Dependence Fortieth Meeting. [online] Available at: https://www.who.int/medicines/access/controlled-substances/WHOCBDReportMay2018-2.pdf [Accessed 17 Jul. 2019].
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