Adaya

MEDICINAL
CANNABIS OIL

PRODUCT
INFORMATION

GOOD MANUFACTURING PRACTICE
AU GMP
CERTIFIED

MEDICINE SUMMARY:

Name:
Adaya 10:10

Description:
Medium Chain Triglyceride (MCT) Oil, Cannabis Extract 30mL vial

Each Medicinal Cannabis Oil bottle contains:
10 mg/mL THC (Delta-9-Tetrahydrocannabinol)
10 mg/mL CBD (Cannabidiol)
Adaya 10:10 is not registered on the Australian Register of Therapeutic Goods (ARTG). No specific indications are approved for the use of this product.
Adaya 10:10 is only available via the Special Access Scheme (SAS) or the Authorised Prescriber (AP) scheme.

INDICATIONS:

Adaya 10:10 does not have approved indications. To date, the Therapeutic Goods Administration (TGA) has approved Medicinal Cannabis SAS applications for indications including, but not limited to, the following:

- chemotherapy-induced nausea and vomiting
- refractory paediatric epilepsy
- symptom relief in palliative care, including non-cancer related palliation
- cancer pain
- neuropathic pain, including that related to multiple sclerosis
- spasticity from neurological conditions such as multiple sclerosis
- anorexia and wasting associated with chronic illness
- Parkinson's Disease
- mental health disorders

Adaya 10:10 should be used as a treatment for specific medical conditions and clinical indications determined by your Medical Practitioner.

Cannabis contains substances that affect the brain and body, including THC and CBD. THC is responsible for the intoxicating and psychoactive effects of cannabis. It may also be responsible for some of the medicinal effects such as reducing nausea, vomiting, pain and muscle spasms as well improvements in sleep and appetite. CBD is not known to be intoxicating.

CONTRAINDICATIONS:

Adaya 10:10 may be contraindicated in patients:

- with hypersensitivity to cannabinoids or to any of the excipients
- who are pregnant or are planning to become pregnant
- who are breast-feeding
- who have known or suspected history or family history of schizophrenia, or other psychotic illness; history of severe personality disorder or other significant psychiatric disorder other than depression associated with an underlying condition
- who have unstable cardiovascular disease

Prior to taking Adaya 10:10 you should disclose to your Medical Practitioner if any of the circumstances described above are applicable to you.

SIDE EFFECTS:

Like all prescription medicines, medicinal cannabis products can have side effects. These may include, but are not limited to:

- fatigue and sedation
- vertigo
- nausea and vomiting
- fever
- appetite increase or decrease
- dry mouth
- diarrhoea
- convulsions
- feelings of euphoria (intense happiness) or feeling dissatisfied
- depression
- confusion
- hallucinations or paranoid delusions
- psychosis or cognitive distortion (having thoughts that are not true)

The extent of side effects can vary with the type of medicinal cannabis product and between individuals. Stop using Adaya 10:10 and consult your Medical Practitioner immediately if you begin to experience any negative side effects.

SAFETY:

- Don't drive or operate heavy equipment after using Adaya 10:10
- Adaya 10:10 can cause drowsiness and impair your ability to concentrate and make quick decisions so consider, with your Medical Practitioner, when the optimal time is to use Adaya 10:10
- Avoid frequent use unless advised by your Medical Practitioner
- Avoid combining Adaya 10:10 with alcohol and/or other CNS depressants/ sedatives (including prescription medications, e.g. benzodiazepines). Using cannabis at the same time as alcohol and/or other sedative drugs can cause more severe levels of impairment and adverse effects

The higher the THC content in a product, the higher the likelihood of experiencing adverse effects/poisoning, especially if you are a first-time or inexperienced user.

If you have consumed cannabis and are experiencing particularly unpleasant or harmful effects stop using it and speak with your Medical Practitioner.
In the event of an adverse event please contact the Therapeutic Goods Administration (www.tga.gov.au/reporting-problems).

DOSAGE & ADMINISTRATION:

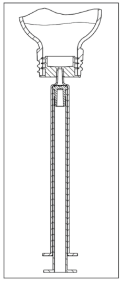
There is currently no scientifically defined dose for Adaya 10:10 in any specific medical condition, and effects remain individualised. **Do not use Adaya 10:10 without receiving dosage and administration advice from your Medical Practitioner.**

When medicating with cannabis oil, it is important to note there is an extended onset time and longer duration of effects.

Each bottle of Adaya 10:10 includes a dosing syringe and a syringe adaptor to aid dosing.

Dosing of Adaya 10:10 is individualised and the rate and speed of dose adjustment is dependent on each individual's response. It is recommended to start low and titrate the dose slowly. The optimal dose is the lowest dose that achieves the highest benefit.

INSTRUCTIONS FOR USE:



1. Unscrew the cap located on the bottle. If this is your first use, insert the clear bottle adaptor with the small hole in the centre into the bottle.
2. Insert the tip of the syringe into the bottle adaptor and press down until it is snug.
3. Invert the bottle so that the top of the bottle with the attached syringe is facing downward.
4. Draw up the prescribed into the syringe by pulling back the plunger so that the black line aligns with the medication dose.
5. Turn the bottle upright and remove the syringe by pulling up on the barrel.
6. Aim the tip of the syringe into the mouth and depress the plunger into the barrel. Swallow the dose.
7. To wash the syringe, separate the plunger from the barrel and wash with warm water. Allow it to dry completely before the next dose.

OVERDOSAGE:

The signs of an overdose may include, but are not limited to:

- chest pain
- rapid heartbeat
- nausea/vomiting
- psychotic episode
- respiratory depression
- severe anxiety and/or panic attack
- ataxia (loss of full control of bodily movements)
- slurred speech
- coma

Children are at greater risk of poisoning. For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

DRIVING AND USE OF MACHINERY:

If you have consumed cannabis, do not drive or operate machinery.
There is no guidance to drivers about:

- how much cannabis can be consumed before it is unsafe to drive
- how long a driver should wait to drive after consuming cannabis

Drug-driving is a criminal offence, and you should discuss the implications for safe and legal driving with your Medical Practitioner.

STORAGE CONDITIONS:

Store in a cool, dry place away from direct sunlight
Keep out of reach of children
Use within the expiry date indicated on the label and packaging

SPONSOR:

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DATE OF INFORMATION:

This information was prepared in August 2020 Version 2.0

WARNING:

THIS MEDICINAL CANNABIS PRODUCT IS A SCHEDULE 8 POISON:
CONTROLLED DRUG
POSSESSION WITHOUT AUTHORITY IS ILLEGAL
KEEP OUT OF REACH OF CHILDREN

If you have any other questions about medicinal cannabis products, please talk to your Medical Practitioner.