



## CONSUMER MEDICINE INFORMATION (CMI)

### 25:25 SATIVA OIL

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#### PRODUCT DETAILS

Alfie 25:25 Sativa Oils are a medicated oil containing the active ingredients Delta-9- Tetrahydrocannabinol (THC), Cannabidiol (CBD).

Active ingredients:

- THC 25mg/ml (delta-9-tetrahydrocannabinol)
- CBD 25mg/ml (cannabidiol)

The medicine name is Alfie 25:25 Sativa Oil and is only available with a Doctor's prescription.

#### WHY AM I USING ALFIE THERAPEUTICS?

The Therapeutic Good Administration (TGA) has approved Special Access Scheme (SAS) applications for medicinal cannabis products including, but not limited to, the below:

- Chemotherapy induced nausea and vomiting (CINV)
- Anxiety
- Cancer pain
- Palliative care
- Neuropathic and chronic pain
- Refractory pediatric epilepsy
- Post Traumatic Stress Disorder (PTSD)
- Insomnia and sleep disorders
- Anorexia and wasting associated with chronic illness (e.g., Cancer)
- Spasticity from neurological conditions (e.g., Multiple Sclerosis)

Possession of medicinal cannabis products without authority is illegal and Alfie Therapeutics should only be used to treat specific conditions or symptoms as authorised by your Doctor.

#### WHAT SHOULD I KNOW BEFORE USING ALFIE THERAPEUTICS?

Do not use Alfie Therapeutics if:

- You have had an allergic reaction to medicinal cannabis products in the past
- You are allergic to THC (delta-9-tetrahydrocannabinol) or CBD (cannabidiol)
- The expiry date has passed
- The packaging is damaged or shows signs of tampering

Always check the ingredients to ensure you can use this medicine.

Tolerance or dependence on Alfie Therapeutics is unlikely but may occur in some persons.

Psychoactive side effects attributed to THC may occur in some persons.

Alfie Therapeutics is contraindicated for:

- Women who are pregnant or lactating
- Patients with liver or kidney dysfunction (consult with your Doctor)
- Patients with cardio-pulmonary disease (consult with your Doctor)
- Patients with family history of schizophrenia
- Patients with a diagnosed history of psychosis and/or active mood disorders
- Patients with a history of serious psychiatric disorders including but not limited to schizophrenia or psychosis, unless specifically prescribed by a qualified healthcare professional with a knowledge of your psychiatric history

There may be other contraindications not yet known due to limited scientific information.

#### WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with Alfie Therapeutics and its effectiveness.

Ensure you consult with your doctor or pharmacist if you are currently using or have recently used any other medications or if you have any known food intolerances. Alfie Therapeutics may interact with other drugs or some foods.

**If you have not yet informed your Doctor about any other medications or food allergies, tell them before you begin using Alfie Therapeutics.**

## WHAT SHOULD I KNOW WHILE USING ALFIE THERAPEUTICS?

### STORAGE

All medicines (including cannabis medicines) must be stored safely in a location that children and animals cannot reach. Light and heat can degrade cannabis products. Store all cannabis products in a cool dark place below 25°C. Do not transfer product material to a different container. Do not use product after the expiry date printed on the label.

### SAFETY INFORMATION

Alfie Therapeutics is a medicinal cannabis product that contains THC (delta-9-tetrahydrocannabinol), is psychoactive and may lead to temporary cognitive impairment. Patients are advised not to drive or operate any complex machinery for 24 hours after administering medicines containing THC.

Do not consume alcohol whilst taking Alfie Therapeutics.

Always consult with your doctor prior to administration of medicinal cannabis products. Remind any doctor, dentist or pharmacist you visit that you are using Alfie Therapeutics.

### CHILDREN AND ADOLESCENTS

Alfie Therapeutics should not be used by children or adolescents under the age of 18 years old unless prescribed under the supervision of a registered healthcare practitioner.

### OVERDOSE

In line with TGA recommendations of "start low, go slow" there may be a potential for patients to ingest more medicinal cannabis than is suitable for them, which may lead to discomfort. Adverse effects associated with ingesting too much medicinal cannabis are generally temporary and self-resolving upon cessation.

## HOW DO I USE ALFIE THERAPEUTICS?

### DOSING AND ADMINISTRATION

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Always use 25:25 Sativa Oil as per your doctor's instructions.

Do not take more than 12mL in 24 hours. It is recommended to take 25:25 Sativa Oil with or after food.

Only a doctor can start you on treatment with 25:25 Sativa Oil.

Your doctor will assess you from time to time to see if you should continue with your treatment. Continue to use this medicine for as long as your doctor advises you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist. If you forget to use it do not increase dose to make up for a missed dose. If you have trouble remembering when to use your medicine, speak with your pharmacist or doctor.

The bottle of 25:25 Sativa Oil includes an oral syringe and stopper. The syringe must be regularly cleaned with soap and water.

### DIRECTIONS

**Step 1:** Remove the cap and the tamper-evident seal from the bottle.

**Step 2:** Insert the syringe into the small hole in the stopper.

**Step 3:** With the syringe inserted, turn the bottle upside down and extract the required amount of 25:25 Sativa Oil into the syringe.

**Step 4:** Insert the syringe in the mouth and depress the plunger until the entire contents of oil are released from the syringe into the mouth for oral ingestion.

## SIDE EFFECTS

Like all medicines, Alfie Therapeutics may produce unwanted side effects in some people. Side effects are more common when you start your treatment. They are usually mild and temporary, wearing off within a few hours. Rare side effects that warrant immediate cessation of Alfie Therapeutics are:

- Depression or suicidal thoughts
- Seizures or convulsions
- Difficulty breathing
- Paranoia

- Hallucinations (auditory/visual)
- Fainting, lightheadedness and dizziness associated with low blood-pressure

**Notify your Doctor immediately, or proceed to the nearest hospital, if you experience any of the above symptoms.**

More common side effects associated with taking medicinal cannabis products for the first time, or from increasing usual dosing, are mild and transient in nature and include:

- Headaches
- Blurred vision
- Dry mouth
- Nausea
- Increased heart rate or palpitations
- Occasional or brief paranoid thoughts
- Euphoria or other cognitive effects
- Confusion or problems concentrating
- Coughing or phlegm
- Drowsiness
- Anxiety

If any of the above side effects are experienced for a prolonged period of time (i.e., greater than 24 hours) or if severe, immediately stop taking Alfie Therapeutics and consult your doctor or pharmacist or seek immediate medical attention.

**This list does not serve as a complete list of potential adverse effects. If you experience any unexpected serious adverse effects not listed, stop using Alfie Therapeutics immediately and contact your Doctor or seek immediate medical attention. Reporting adverse effects assists us to provide more information on the safety of this product.**

## **SPONSOR INFORMATION**

Alfie Therapeutics  
Suite 1333  
17 Gould Road  
Herston, 4006 QLD

E: [support@alfietherapeutics.com](mailto:support@alfietherapeutics.com)  
W: [www.alfietherapeutics.com](http://www.alfietherapeutics.com)

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