



## CONSUMER MEDICINE INFORMATION (CMI)

### BALANCED 25:25

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#### PRODUCT DETAILS

Balanced 25:25 is an oral liquid which contains approximately 25mg of THC and 25mg of CBD per mL.

Active ingredients:

- THC 2500mg (delta-9-tetrahydrocannabinol)
- CBD 2500mg (cannabidiol)

Other ingredients:

- MCT Oil

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

#### WHY AM I USING BALANCED 25:25?

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

- Depression
- Anxiety
- Epilepsy
- Neuropathic and chronic pain
- Inflammatory Diseases
- Autism
- Parkinsons
- Rheumatoid Arthritis
- Endometriosis
- Autism
- Migraine
- Fibromyalgia

Possession of medicinal cannabis products without authority is illegal and Balanced 25:25 should only be used to treat specific conditions or symptoms as authorised by your Doctor.

#### WHAT SHOULD I KNOW BEFORE USING BALANCED 25:25?

Do not use Balanced 25:25 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), or MCT (medium-chain triglyceride) coconut oil
- 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 Balanced 25:25 is unlikely but may occur in some persons.

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

Balanced 25:25 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 Balanced 25:25 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. Balanced 25:25 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 Balanced 25:25.**

## WHAT SHOULD I KNOW WHILE USING BALANCED 25:25?

### 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 to a different container. Do not use product after the expiry date printed on the label.

### SAFETY INFORMATION

Balanced 25:25 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 Balanced 25:25.

Always consult with your doctor prior to administration of medicinal cannabis products. Remind any doctor, dentist or pharmacist you visit that you are using Balanced 25:25.

### CHILDREN AND ADOLESCENTS

Balanced 25:25 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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much Balanced 25:25. Follow these instructions even if there are no signs of discomfort or poisoning.

If you accidentally use more of this medicine than prescribed, you may:

- Feel dizzy, sleepy or confused.
- Feel your heart rate change.

If you experience any of the above symptoms, and they become concerning to you, speak with your doctor or pharmacist.

## HOW DO I USE BALANCED 25:25?

### DOSING AND ADMINISTRATION

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

Do not take more than 12mL in 24 hours.

It is recommended to take Balanced 25:25 with or after food.

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

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 Balanced 25:25 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 Balanced 25:25 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.

### TITRATION

A titration period may be required to reach your optimal dose and your doctor will provide you with a treatment schedule based on your needs.

## SIDE EFFECTS

Like all medicines, Balanced 25:25 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 Balanced 25:25 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 Balanced 25:25 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 Balanced 25:25 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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