

CIRCLE BALANCE 25:25 - CONSUMER MEDICINE INFORMATION

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Circle BALANCE 25:25. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits, if you have any concerns about taking this medicine, ask your doctor or pharmacist.

WHAT IS MEDICINAL CANNABIS OIL

Pharmaceutical grade, natural, plant-based medication, containing full-spectrum cannabis concentrates diluted in MCT oil. Each product contains a combination of the active ingredients CBD (cannabidiol) and THC (delta-9-tetrahydrocannabinol). Ingredients are cultivated and extracted from cannabis plants that have been specifically bred and grown to suit relevant medical conditions. Cannabis oils are designed for oral administration to achieve accuracy of dosing and a longer-lasting effect.

MEDICINE NAME

Circle BALANCE 25:25 Cannabis Oil, 30mL

MEDICINE DESCRIPTION

Each Medicinal Cannabis Oil bottle contains:
25 mg/mL CBD (Cannabidiol)
25 mg/mL THC (Delta-9-Tetrahydrocannabinol)

Circle BALANCE 25:25 is not registered on the Australian Register of Therapeutic Goods (ARTG). No specific indications are approved for the use of this product. Circle BALANCE 25:25 is only available via the Special Access Scheme (SAS) or the Authorised Prescriber (AP) scheme.

INDICATIONS

Circle BALANCE 25:25 does not have approved indications. However, the Therapeutic Goods Administration (TGA) has approved Medicinal Cannabis SAS applications for indications including, but not limited to the following;

- Anxiety-related disorders
- Neuropathic pain including Fibromyalgia
- Chronic pain
- Chemotherapy-induced nausea and vomiting
- Rheumatological conditions
- Paediatric epilepsy
- Symptom relief in palliative care
- Depression
- Cancer pain
- Insomnia
- Multiple sclerosis
- PTSD
- IBS
- Crohn's Disease
- Anorexia and wasting associate with chronic illness
- Parkinson's Disease

Circle BALANCE 25:25 should be used to treat specific medical conditions and symptoms determined by your Medical Practitioner.

CONTRAINDICATIONS

Circle BALANCE 25:25 may be contraindicated in patients:

- With hypersensitivity to cannabinoids or any of the excipients
- Who are pregnant, planning to become pregnant or lactating
- Who have a known history of schizophrenia or significant psychiatric disorder other than depression
- Who have severe, unstable cardiovascular disease

SIDE EFFECTS

All medicines may have unwanted side effects. Sometimes they are serious, but most of the time they are not. As for other medicines of this type, many side effects tend to be minimal and reduce over time. These side effect may include, but are not limited to:

- Nausea and vomiting
- Dizziness
- Vertigo
- Fever
- Diarrhoea
- Convulsions
- Feelings of euphoria
- Confusion
- Impaired coordination
- Changes in appetite
- Drowsiness and sedation
- Impaired short-term memory
- Dry mouth
- Hives
- Psychosis

Your doctor has weighed the risks of this medicine against the benefits they expect it will have for you. The extent of side effects will vary between individuals. Stop using Circle BALANCE 25:25 and talk to your Medical Practitioner if you experience any negative side effects.

SAFETY

- Tell your doctor if you have allergies to other medicines or have had any medical conditions, especially the following: unstable cardiovascular disease or a history of psychosis
- Tell your doctor if you have used cannabis previously
- Do not drive or operate heavy machinery while after using Circle BALANCE 25:25
- Avoid combining Medicinal Cannabis Oil with other CNS depressants like benzodiazepines, sedatives and alcohol. Using Circle BALANCE 25:25 at the same time as sedatives may cause impairment or adverse effects.

- If you experience any signs of allergic reaction like skin rash, hives, swelling of the face, lips, tongue, difficulty breathing or shortness of breath, urgently call your doctor.

Side effect and adverse effects are generally associated with THC rather than CBD. The higher the amount of THC content in a product, the higher the likelihood of experiencing adverse effects.

If you have consumed Circle BALANCE 25:25 and are experiencing particularly harmful side effects, immediately 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 AND ADMINISTRATION

Dosage is dependent on the specific medical condition, do not use Circle BALANCE 25:25 without dosage and administration advice from your Medical Practitioner. When using Medicinal Cannabis Oil, there is an extended onset time and longer duration of effects.

Each bottle of Circle BALANCE 25:25 includes a dosage syringe and a syringe adaptor to aid dosing. It is recommended to start on a low dose and titrate the dose up slowly. The optimal dose is the lowest dose that achieves the highest benefit.

INSTRUCTIONS FOR USE

- Unscrew the cap on the bottle. If this is your first use, insert the clear bottle adaptor in the small hole in the centre of the bottle (if not already preinserted)
- Insert the tip of the syringe into the bottle adaptor and press down until it is securely inserted
Invert the bottle so that the top of the bottle with the attached syringe is facing downwards
- Draw up the prescribed dosage into the syringe by pulling back the plunger, the black line should align with the prescribed dosage
- Turn the bottle upright and remove the syringe by pulling up on the barrel
- Aim the tip of the syringe into the mouth and depress the plunger, swallow the dose
- Wash the syringe by separating the plunger from the barrel and wash with warm, clean water. Allow it to dry before the next dose

OVERDOSAGE

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

- Ataxia
- Psychotic episode
- Chest pain
- Rapid heartbeat
- Respiratory depression
- Nausea and vomiting
- Severe anxiety attack
- Severe panic attack
- Slurred speech

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

STORAGE

Keep your medicine in a secure area out of reach of children. Keep your medicine in a cool, dry place where the temperature stays below 25°C. Use within the expiry date as indicated on the label.

SPONSOR

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DATE OF INFORMATION

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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 Circle BALANCE 25:25, please talk to your Medical Practitioner.