

Edison CBD 50 Pastille - 30pk

Australian Product Information

1 Name of the Medicine

Edison CBD 50 Pastille - 30pk

2 Qualitative and Quantitative Composition

Edison CBD 50 Pastille - 30pk are a pectin-based, vegan-friendly oral pastille containing CBD 50 mg per pastille, offering a high-strength CBD option in a precise, unit-dosed format.

Each pastille of Edison CBD 50 Pastille - 30pk contains:

- Active Ingredients:
 - 50 mg cannabinal (CBD)
- Product contains other non-active ingredients including Sugar, Glucose syrup, Water, Pectin, Fractionated coconut oil, Natural flavour, Citric acid, Colour (102,122,124). Contains Tartrazine
- The flavour profile features ripe, juicy mango notes, delivering a smooth and rounded fruit-forward taste.
- Pastilles each weigh 3 g.

Each jar contains 30 pastilles:

- Cannabinoids per jar: CBD 1,500 mg

3 Pharmaceutical Form

Edison CBD 50 Pastille - 30pk are puck-shaped, yellow coloured, mango flavour Pastilles. Each pastille contains 50 mg cannabinal (CBD).

4 Clinical Particulars

4.1 Therapeutic Indications

Edison CBD 50 Pastille - 30pk is not registered on the Australian Register of Therapeutic Goods (ARTG), so there are no specific indications approved for its use.

Edison CBD 50 Pastille - 30pk is only available via. the Special Access Scheme (SAS-B) or the Authorised Prescriber (AP) scheme and should be used as a treatment for specific medical conditions and clinical indications by the authorised prescribing healthcare professional.

4.2 Dose and Method of Administration

Edison CBD 50 Pastille - 30pk is intended for oral administration. The recommended starting dose is half of the pastille or the lowest effective dose, administered when required. The dose may be increased gradually if necessary, based on individual patient response and tolerability.

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Dosing and titration of medicinal cannabis pastille products should be individualised and conducted under the supervision of a qualified healthcare professional to determine the optimal therapeutic dose for each patient.

TITRATION PERIOD

A titration period is required to reach the optimal dose. The amount and timing of the medication will vary between patients. The optimal dose for Edison CBD 50 Pastille - 30pk has not been established. It is important to “start low and go slow” to minimise the risk of side effects. The optimal dose may vary depending on the patient, and it may take up to 1–2 months of up-titration before achieving the optimal dose.

Example of Patient Dosing Titration Schedule

DAY	1st Dose	2 nd Dose	3rd Dose	Daily Dose (TOTAL)
DAY 1-3	1			1
DAY 4-6	1			1
DAY 7-9	1	1		2
DAY 10-13	1	1		2
DAY 14+	2	2		4

Continue to titrate the dosage as required to achieve therapeutic benefit.

Healthcare professionals may wish to consider adding a 3rd dose earlier as required.

MAINTENANCE PERIOD

The optimal dose is the lowest dose that achieves the highest benefit established during the titration period. This dose should be maintained during treatment. Re-titration (up or down) may be required depending on any changes to the patient’s concurrent medications or any tolerance concerns or adverse events.

METHOD OF ADMINISTRATION

Edison CBD 50 Pastille - 30pk are intended for oral administration.

It is best to take Edison CBD 50 Pastille - 30pk with food.

4.3 Contraindications

Edison CBD 50 Pastille - 30pk are contraindicated in:

- Patients with allergies or hypersensitivity to the active substances or to any of the excipients.
- Patients with unstable cardiovascular disease.
- Patients with any known or suspected family history of schizophrenia, or other psychotic illnesses.
- Patients with previous psychotic or concurrent active mood or anxiety disorders.
- Who are pregnant or breastfeeding [see 4.8 Effects on fertility, use in pregnancy and lactation].

4.4 Special Warnings and Precautions for Use

IDENTIFIED PRECAUTIONS

- Patients under 18 years of age.
- Severe liver or renal disease.
- Drug dependency (including nicotine and heavy alcohol consumption).
- Other medications (especially sedatives such as opioids and benzodiazepines).
- Elderly patients (as metabolism in the elderly is slower and they may be more sensitive to the pharmacological effects of cannabis).

USE IN HEPATIC AND RENAL IMPAIRMENT

No specific studies have been carried out on hepatic and renal impairment. The effects of Edison CBD 50 Pastille - 30pk may be exaggerated or prolonged and frequent clinical evaluation by a clinician is recommended in this patient population.

USE IN THE ELDERLY

No specific studies have been carried out in elderly patients, however, as elderly patients may be more prone to develop potential CNS adverse reactions, care should be taken.

PAEDIATRIC USE

No specific studies have been carried out on paediatric patients. Edison CBD 50 Pastille - 30pk should not be prescribed for children and adolescents under 18 years of age.

EFFECTS ON LABORATORY TESTS

No data available.

4.5 Interactions with other medicines and other forms of interactions

Cannabis is metabolised via the hepatic cytochrome pathway and excreted via the biliary tract in faeces, along with urinary excretion of acid metabolites. Because the Cytochrome P450 (CYP450) enzyme system is implicated in the metabolism of THC and CBD, there are likely to be significant pharmacokinetic interactions, particularly with drugs that are metabolised by, or either inhibit or induce CYP450 enzymes.

The clinical significance is greater for medications that have a narrow therapeutic window such as warfarin. THC also has the potential to inhibit CYP isozymes 3A4, 3A5, 2C9, and 2C19, while CBD has the potential to inhibit CYP 2C19, 3A4, and 3A5.

It is possible that the bioavailability of drugs that are metabolised by these isozymes may increase with concurrent medicinal cannabis consumption, e.g., anticoagulants (warfarin, apixaban, rivaroxaban), amitriptyline, phenytoin, theophylline, granisetron, dacarbazine, and flutamide.

Medications that may reduce the effect of Edison CBD 50 Pastille - 30pk include:

- Medications to treat inflammation, including asthma (e.g. Prednisone, Pulmicort).
- Medications to treat seizures.

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- Some medications to treat depression or anxiety disorders, some antibiotics, some contraceptives, some HRT medications.
- Dabrafenib (Tafinlar) to treat cancer.
- Hydrocortisone.
- Aspirin.
- St John's Wort.

4.6 Fertility, pregnancy and lactation

No data is available; however, Edison CBD 50 Pastille - 30pk is not recommended for women who are pregnant, planning to become pregnant, or breastfeeding.

4.7 Effects on ability to drive and use machines

Cannabinoids may impair the ability to drive and operate machinery because they may cause somnolence and sedation. Edison CBD 50 Pastille - 30pk is a full spectrum cannabis product and therefore does contain trace amounts of THC which may be detected in drug tests.

4.8 Adverse effects (Undesirable effects)

No data specific to Edison CBD 50 Pastille - 30pk is currently available.

Adverse reactions to Edison CBD 50 Pastille - 30pk may include, but are not limited to:

- Abnormal thoughts/cognitive impairment
- Appetite changes
- Muscle weakness
- Dizziness
- Dry mouth
- Fatigue
- Malaise
- Nausea
- Paranoia
- Drowsiness
- Blurred vision
- Tachycardia

Long-term use may increase the risk of triggering or aggravating psychiatric and/or mood disorders, negatively affect cognitive function (ability to think or make decisions) or decrease the beneficial effects of Edison CBD 50 Pastille - 30pk (tolerance).

Special attention should be taken with patients that present with any of the following undesired side-effects with Edison CBD 50 Pastille - 30pk:

- Paranoia
- Hallucinations
- Rapid or irregular heartbeat
- Hypotension associated with light-headedness,
- Dizziness, or fainting.
- Seizures (if you do not have a history of epilepsy)
- Depression or suicidal ideation

4.9 Overdose

Accidental ingestion of greater doses than prescribed may result in an increase in adverse events or in drug-drug interactions. In the event of a higher dose relating to an adverse event/s, patients should immediately contact their:

- Healthcare Provider, or
- the Poisons Information Centre on 13 11 26 (Australia), or
- go to their nearest Hospital Emergency Department.

In the case of an overdose, treatment should be symptomatic and supportive. For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 Pharmacological Particulars

5.1 Pharmacodynamic Properties

PHARMACOTHERAPEUTIC GROUP

Other Analgesics

ATC CODE – N02BG10

MECHANISM OF ACTION

Cannabinoids, the main active components of cannabis, interact with cannabinoid receptors (CB1 and CB2) in the endogenous endocannabinoid system, or ECS.

CB1 receptors are the most abundant of the two receptor types, predominantly found in the central nervous system (CNS), and in regions responsible for cognitive function. CB2 receptors are prevalent in the immune and peripheral nervous systems playing a crucial role in maintaining physical well-being by regulating functions such as immunity, inflammation, and pain.

Delta-9-tetrahydrocannabinol (THC) is the major psychoactive component of cannabis and interacts with both CB1 and CB2 receptors. When combined with CBD, the psychoactive characteristics of THC are diminished.

CLINICAL TRIALS

No data available.

5.2 Pharmacokinetic Properties

Pharmacokinetic (PK) or Pharmacodynamic (PD) data has not been obtained for Edison CBD 50 Pastille - 30pk PK parameters may vary considerably from patient to patient. Most data on the PK and PD profiles of cannabis are extrapolated from THC studies.

ABSORPTION

Cannabis products consumed orally are more slowly absorbed compared to those consumed via inhalation. The bioavailability of oral cannabis may be lower than via inhalation (ranging from 10-20%), primarily due to factors such as first-pass metabolism in the liver & individual differences in metabolism

and physiology. The onset of effect is usually slow, with peak onset occurring 2-4 hours after oral consumption, with effects lasting from 8-12 hours.

DISTRIBUTION

Cannabinoids are distributed throughout the body; they are highly lipid soluble and accumulate in fatty tissue. The release of the cannabinoids from fatty tissue is responsible for the prolonged terminal elimination half-life.

Due to its high lipid solubility, THC has a large apparent volume of distribution, approximately 10 L/kg, and the plasma protein binding of THC is mainly bound to low-density lipoproteins, with up to 10% present in red blood cells, while its metabolite, 11-OH-THC, is strongly bound to albumin with only 1% found in the free-fraction.

METABOLISM

THC and CBD are metabolised in the liver by CYP isoenzymes, including CYP2C9, CYP2C19, CYP2D6, and CYP3A4. They may be stored for as long as 4 weeks in the fatty tissues from which they are slowly released at sub-therapeutic levels back into the blood stream and metabolised via the renal and biliary systems.

The predominant phase 1 metabolites of THC are 11-hydroxy-THC (11-OH-THC) and 11-nor-9-carboxy-THC (THC-COOH), which undergo phase 2 glucuronidation to produce cannabinoid glucuronides.

CBD undergoes a significant first-pass effect leading to the formation of several metabolites, most notably, 7-carboxy-CBD (7-COOH-CBD).

EXCRETION

Approximately 65% of the excretion of THC and its metabolites occurs via the faeces and 20% via urine. After 5 days, approximately 80% to 90% of the total dose is excreted. Unlike THC, a large proportion of CBD is excreted unchanged in the faeces. The CBD half-life is estimated to be 20–36 hours.

Cannabinoids and their metabolites are excreted slowly due to their slow movement out of body fat and other tissues back into the bloodstream. Therefore, they can sometimes be found in urine and faeces for several weeks post-administration.

5.3 Preclinical Safety Data

Edison CBD 50 Pastille - 30pk has not been evaluated in preclinical studies.

GENOTOXICITY

No genotoxicity studies have been undertaken with Edison CBD 50 Pastille - 30pk.

CARCINOGENICITY

No carcinogenicity studies have been undertaken with Edison CBD 50 Pastille - 30pk.

6 Pharmaceutical Particulars

6.1 List of Excipients

[insert excipients here]

Refer to Section 2 - Qualitative and quantitative composition. [optional]

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified. [optional]

6.3 Shelf Life

For storage conditions and expiration dates, please refer to the Edison CBD 50 Pastille - 30pk product label.

6.4 Special Precautions for Storage

- Store below 25 °C. Keep out of direct sunlight.
- Do not use this product after the expiry date, which is stated on the container. The expiry date corresponds with the last day of the month indicated.
- Keep out of reach of children.

6.5 Nature and contents of container

Name Edison CBD 50 Pastille - 30pk

Form Pastilles

Pack Size 30 pieces per pack. Each piece provides 50 mg/g cannabinoI (CBD).

Container Jar with tamper evident seal/child resistant closure

6.6 Special Precautions for Disposal

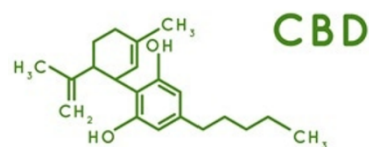
It is recommended that expired or opened EDISON 30ct CBD Pastilles – Mango – 3g Pastille should be returned to the pharmacy for disposal. Do not throw away this product via wastewater or household waste; ask your pharmacist how to dispose of this product as proper disposal will help protect the environment.

6.7 Physicochemical Properties

Chemical Structure

Cannabidiol (CBD)

- Molecular formula: C₂₁H₃₀O₂
- Resorcinol ring fused with a p-menthane ring (open pyran)
- Key functional groups: Two hydroxyl (-OH) groups
- Description: Non-psychoactive; modulates cannabinoid receptor activity and other signalling pathways
- CAS Number: 13956-29-1



7 Medicine Schedule (Poisons Standard)

POISON SCHEDULE

CONTROLLED DRUG – SCHEDULE 4.

POSSESSION WITHOUT AUTHORITY IS ILLEGAL. KEEP OUT OF REACH OF CHILDREN.

CATEGORY OF ACTIVE INGREDIENTS – CATEGORY 4.

PRESCRIPTION ONLY MEDICINE.

TGA UNAPPROVED MEDICINAL CANNABIS PRODUCTS.

8 Sponsor

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EDISON 30ct CBD Pastilles – Mango – 3g Pastille is an unapproved medicine and is not included in the Australian Register of Therapeutic Goods (ARTG).

9 Date of First Approval

Version 1: January 30, 2026

10 Date of Revision

Executed Version 1 Dated January 30th currently In Force

Section Changed	Summary of New Information