



THC 10mg: CBD 10mg: CBG 10mg



Therapeutic Effects

Analgesic

Anti-inflammatory

Anxiolytic

Anti-depressant

Anti-nausea Anti-emetic

Conditions

Chronic Pain

Anxiety Insomnia PTSD

Nausea & Vomiting

SPONSOR

Nectar Portfolio

SIZE

24 Pastilles

**FORMAT** 

Pastille

FLAVOUR Rapid Blueberry

CATEGORY

Category 4

ACTIVE INGREDIENTS

Tetrahydrocannabinol (THC) 10mg

Cannabidiol (CBD) 10mg Cannabigerol (CBG) 10mg

SCHEDULE

Schedule 8

# INTRODUCTION

Blüm® Ease pastilles are crafted for the relief of pain, inflammation, and a range of symptoms. Each dose-controlled pastille contains a balanced 1:1:1 ratio of 10mg THC, 10mg CBD, and 10mg CBG, delivering a refreshing Rapid Blueberry flavour.

Blüm flavours are precisely formulated to complement the therapeutic effects of each pastille. By using all-natural ingredients, they effectively mask any cannabis aftertaste, enhancing patient experience and promoting adherence to medication schedules.

The pastilles feature a homogenised mixture, ensuring even distribution of cannabinoids throughout each pastille, making dosing accurate and reliable. This consistent formulation helps alleviate symptoms of anxiety, insomnia, nausea, and vomiting, while providing effective relief from pain and inflammation.

Blüm® Ease features a unique emulsion made from vegan, non-GMO ingredients, natural emulsifiers, and high oleic sunflower oil. Each pastille adheres to Australian medication packaging regulations, including childresistant tins, ensuring compliance and safety for all patients.

# INGREDIENTS

## Non-GMO, Gluten Free, No Artificial Colours

Organic cane sugar, organic clarified brown rice syrup, blueberry puree, water, pectin, blueberry juice concentrate, organic icing sugar, citric acid, natural flavour, sodium citrate, high oleic sunflower oil, THC distillate, CBD isolate, CBG isolate, organic tapioca starch, ascorbic acid, rosemary extract.

# PHARMACOLOGY

#### Mechanism of action

Medicinal cannabis interacts with the human endocannabinoid system via receptors called CB1 and CB2 that are found throughout the nervous system, tissues and immune system. THC is a psychoactive, partial agonist of both CB1 and CB2 receptors. CBD doesn't intrinsically activate CB1 or CB2 receptors but has demonstrated neuroprotective properties due to its anti-oxidant and anti-inflammatory effects.

CBG is a non-psychoactive weak partial agonist at CB1 and CB2 receptors. Pre-clinical findings show that CBG possesses antioxidant, anti-inflammatory effects, and has anti-anxiety, neuroprotective properties.

# Absorption

Medicinal cannabis pastilles are absorbed through the digestive system, which results in a slower onset of effects compared to inhalation. Onset of effects typically begins within 30 minutes to 2 hours after consumption. Peak effects generally occur 1 to 3 hours after ingestion, and the overall duration of effects can last between 4 to 8 hours.

## Metabolism

Medical cannabis is metabolised in the liver and involves the Cytochrome P450 pathway. Elimination is biliary and excretion occurs via the faeces and urine. The half-life of THC is approximately 4 days.

When eaten, the liver converts THC to 11-hydroxy-THC, which is more potent than THC. This conversion happens more with ingestible formats compared to inhaled THC.

## CONDITIONS & SYMPTOMS

The Therapeutic Goods Administration (TGA) Australia has approved Special Access Scheme (SAS) applications including, but not limited to, the following:

- Chemotherapy-induced nausea and vomiting (CINV)
- · Refractory paediatric epilepsy
- Neuropathic and chronic Pain
- Palliative care
- Cancer pain
- Anxiety
- Spasticity from neurological conditions (e.g., multiple sclerosis)
- Anorexia and wasting associated with chronic illness (e.g., Cancer)
- · Insomnia and sleep disorders
- Post-traumatic stress disorder (PTSD)
- Attention-deficit/hyperactivity Disorder (ADHD)
- Depression

#### DOSING & TITRATION

Dosing is highly individual, so patients and doctors should work together to determine the optimal dosing schedule where the medical benefit is maximised for the individual patient's condition or symptoms.

DOSAGE GUIDE	1/2 PASTILLE	1 PASTILLE	1 1/2 PASTILLES	2 PASTILLES
тнс	5mg	10mg	15mg	20mg
CBD	5mg	10mg	15mg	20mg
CBG	5mg	10mg	15mg	20mg

Patients with severe symptoms may be directed by their doctor to take two pastilles per dose to achieve desired relief. Similarly, patients new to medicinal cannabis may consider starting at a lower dose (for example, a half dose) until being titrated up based on monitoring.

Accurate dosing and titration of medicinal cannabis pastilles can be challenging due to a range of factors, including variability in individual metabolism, inconsistent absorption rates, and the delayed onset of effects compared to other administration methods.

If adverse effects such as dizziness occur, then consider reducing dose for a few days before continuing with titration. For reliable dosing of medicinal cannabis, we recommend patients aim to replicate consistently the conditions in which they self-administer medicinal cannabis.

# SAFETY INFORMATION

# Contraindication

- Women who are pregnant, breastfeeding or planning on becoming pregnant.
- · Patients with a familial history of schizophrenia.
- Patients with a diagnosed history of psychosis and/or active mood disorders.
- Patients with unstable cardio-pulmonary disease (consult with your doctor).
- Children or adolescents under 18 years of age.
- Hypersensitivity to cannabinoids

### Interactions with other medication

Possible PK interactions with drugs that are metabolised by, inhibit, or induce the cytochrome P450 pathway. Therefore medicinal cannabis can increase warfarin levels and patients should be monitored.

#### **Precautions**

Patients should be advised not to drive while consuming high-THC medicinal cannabis as it may impair one's ability to drive safely. Consult with individual state laws around driving with detectable levels of THC in the system. Alcohol may increase THC levels when consumed with medicinal cannabis.

Medicinal cannabis should be monitored in patients with severe immune, liver or kidney disease.

#### **Adverse Events**

Like any medicine, Blüm pastilles may produce unwanted side effects in some people. With all medicinal cannabis medications there are potential adverse events that may affect only some patients.

Based on the literature, medicinal cannabis is generally well tolerated. Adverse effects tend to be mild and transient and associated with the starting doses and initial titration.

Common side effects of medicinal cannabis, sometimes experienced when taking it for the first time or when increasing a usual dose, are typically mild and transient and mau include:

- Drowsiness
- Anxietu
- Increased heart rate or palpitations
- Nausea
- · Dry mouth

- Blurred vision
- · Coughing or phlegm
- Confusion or problem concentrating
- Euphoria or other cognitive effects
- Occasional or brief paranoid thoughts

If patients experience any of the above side effects for a prolonged period (i.e., greater than 24 hours) or if they are severe, they should immediately stop taking Blüm and contact your healthcare provider, prescribing doctor or pharmacist or seek immediate medical attention.

Rare side effects that warrant immediate cessation of Blüm are:

- Hallucinations (auditory or visual)
- Paranoia
- · Difficulty breathing
- · Seizures or convulsions
- Depression or suicidal thoughts
- Fainting, light-headedness and dizziness associated with low blood pressure

If patients experience any of the listed side effects, they should discontinue Blüm immediately. Please be aware that this is not an exhaustive list of potential adverse effects.

If any severe or unexpected side effects occur, whether included in this list or not, patients should stop using the medication immediately and consult their doctor or seek immediate medical care.

#### **Reporting Adverse Events**

If you experience any adverse events, including listed rare side effects or common side effects for a prolonged period, please contact your doctor or pharmacist immediately. This also includes any other severe side effects not listed in this leaflet. Reporting adverse effects assists us in providing more information on the safety of this product.

# Contact Information

Sponsor

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