

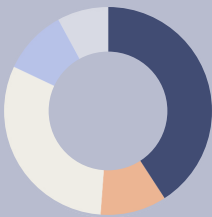
BACIO
GELATO
THC23 INDICA-DOMINANT



TERPENES

- Myrcene
- Caryophyllene
- Humulene
- Farnesene
- Limonene

TOTAL
TERPENE
CONTENT
2.9%



THERAPEUTIC EFFECTS

- Sedative
- Anxiolytic
- Anti-Inflammatory
- Appetite Stimulant

CONDITIONS

- Insomnia
- Anxiety
- Chronic Pain
- PTSD
- Eating Disorders

PACKAGING

- UV-resistant, raw amber glass
- Boveda Terpene Shield included
- Sustainable and recyclable

GROWER Avant Brands

REGION BC, Canada

FORMAT Dried Cannabis Flower

CATEGORY Category 5

SCHEDULE Schedule 8

SIZE 10 grams

INTRODUCTION

Cultiva® – Bacio Gelato is a high-THC (delta-9-tetrahydrocannabinol) indica-dominant strain that is a cross between Sunset Sherbert and Thin Mint Cookies, originally bred by Sherbinskis – a reputable cannabis breeder from North America.

Cultiva Bacio Gelato has frosted, trichome-dense deep purple flowers with green hues and vivid orange pistils. This strain offers a unique and rich 2.9% terpene content with myrcene, caryophyllene, humulene, farnesene and limonene delivering aromas of sweet, skunky gas and vanilla diesel with floral and woody undertones.

This cultivar has been reported by patients to produce a strong, quick-onset cerebral euphoric and relaxing effect – popular for relieving symptoms associated with chronic pain, insomnia, chronic stress, mood management as well as nausea and lack of appetite.

Cultiva Bacio Gelato is available as a dried medicinal cannabis flower and is intended for inhalation using a TGA-approved vaporiser.

PHARMACOLOGY

Cannabinoid Ratio

23% (w/w) THC (mg/g) • <2% (w/w) CBG (mg/g) • <1% (w/w) CBD (mg/g)

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 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.

Absorption

Inhaled medicinal cannabis is rapidly absorbed and has a higher bioavailability than oral administration. Onset of effect is rapid: within 90 seconds. Peak onset occurs 15–30 minutes after inhalation and effects last around 2–4 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.

CONDITIONS AND 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 AND TITRATION

The optimal doses for Cultiva Bacio Gelato will vary for each patient. Each individual should follow a titration process of gradually increasing a dose until the desired result is achieved.

In line with TGA guidance, we recommend following the “start low, go slow” approach whereby patients start with a low dose and slowly increase until the optimal therapeutic result or benefit is achieved.

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. Below is an example of an initial dosing and titration schedule:

DAYS	1-2	3-4	5-6	7-8	9-10	11-12
MORNING (G)	0	0.1	0.1	0.1	0.1	0.1
MIDDAY (G)	0	0	0	0.1	0.1	0.1
EVENING (G)	0.1	0.1	0.1	0.1	0.15	0.15

It may take one to two months of the patient and practitioner working together before the optimal individual dose is established. Accurate dosing and titration of medicinal cannabis flower can be challenging due to a range of factors, including inconsistency in the amount of medicine administered; variance in cannabinoid profiles; discrepancies in temperature during vaporisation; and length and depth of breath when inhaled. 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.

When starting the titration process, patients and doctors should maintain a consistent dosing schedule and adjust dose timing if needed. New medicinal cannabis patients should wait up to 30 minutes between their initial dose before their next inhalation.

This method of repeatable control of dosing should extend to determining the specific milligram value of active cannabinoids within dried medicinal cannabis flower. It is often difficult to attain precise dosing with dried medicinal cannabis flower.

ADMINISTRATION THROUGH INHALATION

The use of a vaporiser to inhale medicinal cannabis is one of the most efficient administration methods for patients. Inhalation offers a rapid onset time, typically providing relief in 5 to 10 minutes, with an expected duration of 2 to 4 hours. This is significantly faster than oral and sublingual ingestion which have an onset period of 1 to 3 hours.

There are several important factors to consider when inhaling medicinal cannabis. Firstly, utilisation of combustion (smoking paraphernalia) is not recommended due to the risk that smoking poses to patients, including potential contribution to chronic obstructive pulmonary disease (COPD). Patients should instead opt to use a TGA-approved vaporiser to heat the dried medicinal cannabis flower below the point of combustion to create smoke-free vapour.

Patients should also be aware that temperature settings with vaporisers will impact their medicinal cannabis. Within the dried cannabis flower, each cannabinoid, terpenoid and flavonoid contains a different boiling point. It should be noted that there are three general temperature bands:

LOW 163°C - 177°C	Cooler vapour temperature, less harsh on the throat Potentially milder subdued psychoactive effects
MEDIUM 177°C - 203°C	Recommended starting temperature
HIGH 203°C - 221°C	Strongest psychoactive effects with maximum extraction of available cannabinoids

SAFETY INFORMATION

Contraindications

- Women who are pregnant, breastfeeding or are 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

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.

Interactions with other medications

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

Adverse events

Like any medicine, Cultiva Bacio Gelato may produce unwanted side effects in some people. With all medicinal cannabis products 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.

The more common side effects associated with taking medicinal cannabis products for the first time or when increasing your usual dose which may be of a more mild and transient nature, may include:

- Drowsiness
- Anxiety
- 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 you experience any of the above side effects for a prolonged period (i.e., greater than 24 hours) or if they are severe, immediately stop taking Cultiva Bacio Gelato and contact your healthcare provider, prescribing doctor or pharmacist or seek immediate medical attention.

Rare side effects that warrant immediate cessation of Cultiva Bacio Gelato 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

Should you experience one or more of the above side effects, stop taking Cultiva Bacio Gelato immediately and either contact your doctor or pharmacist or present at a hospital.

This does not serve as a complete list of potential adverse effects. If you experience any unexpected severe adverse effects that are not listed, stop using the medication immediately and contact your doctor or seek immediate medical attention.

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/Supplier

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