

Australia Consumer Medicine Information (CMI)

SatiVite™ Dried Flower * Eurroka (Sativa Hybrid)

Please read this leaflet carefully before you start using SatiVite™ medicinal cannabis dried flower.

What is a CMI leaflet?

This leaflet answers some common questions about SatiVite's™ medicinal cannabis dried flower. It does not contain all the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using medicinal cannabis dried flower against the benefits he or she expects it will have for you.

If you have any concerns about using this medicine, consult your doctor or pharmacist.

This CMI does not take the place of talking to your doctor or pharmacist.

Keep this leaflet with the medicine as you may need to read it again.

Why prescribe medicinal cannabis dried flower?

There is growing evidence that medicinal cannabis could be beneficial for use when suffering from debilitating conditions, including, but not limited to, chronic pain, pain associated with spasticity in multiple sclerosis (MS), pain associated with cancer in palliative care, chemotherapy-induced nausea and vomiting, refractory paediatric spasticity from neurological conditions, anorexia or wasting associated with chronic illness, sleep disturbance, post-traumatic stress disorder (PTSD), anxiety and refractory epilepsy.

SatiVite™ Dried flower is not approved for treatment of any specific conditions or symptoms. Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you.

The Therapeutic Goods Administration (TGA) has provided patient information (PI) for medicinal

cannabis concerning multiple sclerosis, chronic non-cancer pain, chemotherapy-induced nausea and vomiting in cancer (CINV), and palliative care. The TGA has also released guidance for the use of medicinal cannabis for treatment of epilepsy in paediatric and young adult patients, multiple sclerosis, nausea and vomiting, chronic non-cancer pain, and palliative care. For more information, please visit <https://www.tga.gov.au/community-qa/medicinal-cannabis-products-patient-information>

Your doctor may have prescribed SatiVite™ medicinal cannabis dried flower for another reason.

Ask your doctor if you have any questions about why SatiVite™ medicinal cannabis dried flower has been prescribed for you.

The potential therapeutic and adverse effects associated with medicinal cannabis use may vary depending on the amount of medicinal cannabis used and the medical condition.

SatiVite™ medicinal cannabis dried flower is an unregistered medicine. It is only available for use by you, following approval from the Australian Therapeutic Goods Administration (TGA) Special Access Scheme, applied for by your prescriber.

How does SatiVite™ medicinal cannabis dried flower work?

SatiVite medicinal cannabis dried flower is designed for inhalations and is dosed via a vaporizer. Sourced from Sativa, Indica and hybrid plants, SatiVite™ dried flower contains major cannabinoids including delta-9-tetrahydrocannabinol (Δ^9 -THC) and cannabidiol (CBD), plus a range of terpenes and flavonoids.

With its faster onset of action, inhalation of dried cannabis flower provides rapid bioavailability, however shorter duration of effects compared to ingestion. With inhalation, onset action typically takes between 5 to 10 minutes, with peak effects after 10 to 90 minutes and last for up to 4 hours⁽¹⁾. In contrast, ingestion is slower to take effect but longer lasting.

The effects of medicinal cannabis can vary between patients and can be influenced by a variety of factors including potency, tolerance, frequency of use and delivery mechanisms. It is recommended that a patient administer their dose every day and at consistent times in order to determine the right titration. Dried cannabis and cannabis oils can be used separately or together in achieving desired outcome.

THC is a partial agonist at the most abundant cannabinoid receptors in the body, CB1 and CB2. These G protein-coupled receptors are the modulators for human endocannabinoid system which can elicit symptomatic relief of various disease states through activation of metabolic and neurological pathways. CB1 receptors are found mainly within the central nervous system with CB2 receptors distributed throughout the peripheral organs and immune system.

CBD acts as an antagonist at the CB1 receptor and an inverse agonist at the CB2 receptor. This means it can modify the effects of THC, usually making the effects less severe. CBD is an activator of many other receptors, which can benefit in a number of medical conditions.

The exact mechanism and magnitude of effects of THC and CBD are not fully understood.

As SatiVite™ dried flower contains delta-9-tetrahydrocannabinol, it *may* have psychological effects therefore it is important to take the approach in terms of dosage of **Start Low, Go Slow** in order to achieve the right titration and avoid potential side effects.

What you should know before taking SatiVite™ medicinal cannabis dried flower

Warnings

Do not use if you:

- are allergic to delta 9 or delta 8 tetrahydrocannabinol, cannabidiol, or any of the ingredients listed at the end of this leaflet (refer Product description and ingredients).
- always check the ingredients to make sure you can use this medicine.
- have a serious mental health disorder, such as schizophrenia or psychosis. This does not include depression, anxiety, or post-traumatic stress disorder.
- are pregnant or planning to become pregnant or breastfeeding, unless advised by your doctor.
- have severe heart, immune system, liver, or kidney disease, unless advised by your doctor.

Check with your doctor if you:

- have any other medical conditions such as a serious mental health disorder; this does not include depression, anxiety or post-traumatic stress disorder.
- have severe heart, immune system, liver, or kidney disease.
- take any medicines for any other condition, including non-prescription medication.
- have allergies to any medications, foods, preservatives, or dyes.
- have or have had any liver, kidney, or heart problems.
- have previously abused any drug or substance, including alcohol.
- are under 25 years of age or elderly and have difficulty completing daily tasks.
- need help with transportation or driving to a medical practice or pharmacy.
- are pregnant or planning to become pregnant or breastfeeding, unless advised by your doctor.
- are taking any other medication, including non-prescription medication.

Do not take SatiVite™ medicinal cannabis dried flower after the expiry date has passed.

Do not take SatiVite™ medicinal cannabis dried flower if the packaging is damaged or shows signs of tampering.

Before you start to use SatiVite™ medicinal cannabis dried flower

Tell your doctor if you:

- have allergies to any other medicines.
- have allergies to cannabis, or any other substances such as foods, preservatives, or dyes.
- are pregnant, planning to get pregnant or breastfeeding.
- have liver or kidney problems.
- have a serious heart problem such as angina, a previous heart attack, poorly controlled high blood pressure or a problem with your heart rate or heartbeat.
- have a personal or family history of serious mental disorders such as schizophrenia, psychosis, depression, or bipolar disorder.

If you have not told your doctor about any of the above, tell them before you start using SatiVite™ medicinal cannabis dried flower.

Do not drive or operate machinery when taking medicinal cannabis.

Are you taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop. Some medicines may interfere with SatiVite™ medicinal cannabis dried flower and how it works.

These include:

- Any drugs which slow down the central nervous system, causing drowsiness. These may include sleeping pills, sedatives, some pain medicines, some allergy or cold medicines, antiseizure medicines or alcohol.
- Other drugs may include antiretroviral drugs used in the treatment of conditions such as HIV/AIDS, certain antidepressants, stomach acid inhibitors, certain antibiotics and antifungal medicines, certain

medicines for the heart and herbal medicines.

These medicines may be affected by SatiVite™ medicinal cannabis dried flower or may affect how well medicinal cannabis works, or how well your medicine works. You may need different amounts of your medicine, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these may affect your Treatment plan.

How to use SatiVite™ medicinal cannabis dried flower

How and when to take it

Always use SatiVite™ medicinal cannabis dried flower exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

SatiVite™ medicinal cannabis dried flower is designed for inhalation and is dosed via a vaporiser.

Doses are highly individualised and patients are advised to start with a low dose and gradually increase dosages to achieve the optimal therapeutic outcome (titration). This approach is often termed “**Start Low, Go Slow**”. This is to allow a person to achieve the best relief, whilst minimising side effects of the treatment. The following is a guide for finding the ideal dosage for your condition:

1. Inhale once and wait 15 minutes.
2. If the desired therapeutic effect does not occur, inhale twice and wait 15 minutes.
3. Continue this process increasing the number of inhalations every 15 minutes until the desired therapeutic effect occurs.

The following is a guide for finding the ideal dosage for your condition:

THC Dried flower Titration Schedule – Illustration

	Morning	Midday	Evening
	(g) *	(g) *	(g) *
Day 1-3	0.0	0.0	0.1
Day 4-6	0.1	0.0	0.1
Day 7-9	0.1	0.1	0.1
Day10-12	0.1	0.1	0.15
Day13-15	0.15	0.15	0.15

* *Stop increasing your dose when you find the best dosages*

Once you have identified your optimal dose, record it in a personal dosing diary.

Wait a minimum of 6 to 8 hours between each dose to assess effectiveness and to reduce the potential for unwanted side effects.

Your doctor will work with you to decide the dose of SatiVite™ medicinal cannabis dried flower that best suits you and your symptoms and to minimise any unwanted side effects.

How long to take SatiVite™ medicinal cannabis dried flower?

Your doctor will advise how long you need to take SatiVite™ medicinal cannabis dried flower.

If you forget to take it

Wait until the next dose is due. **Do not take a double dose to make up for the dose that you missed.** This may increase the risk of getting an unwanted side effect.

In case of an overdose

If you take too much (overdose)

Immediately telephone your doctor and/or the Poisons Information Centre (**telephone 13 11 26**) or go to the Emergency Department at your nearest hospital.

Do this even if there are no signs or symptoms of discomfort or poisoning.

Symptoms of overdose may include sleepiness, confusion, disorientation, clumsiness or loss of coordination, fainting, dizziness, chest pain, fast, slow or pounding heartbeat, panic attacks, loss of contact with reality and seizures.

While using SatiVite™ medicinal cannabis dried flower

Things you MUST DO

Stop using SatiVite™ medicinal cannabis dried flower immediately and consult your doctor if you begin to experience any side effects.

If you are about to start on any other new medicine tell your doctor and pharmacist that you are taking SatiVite medicinal cannabis dried flower.

Things you MUST NOT DO

Do not give SatiVite™ medicinal cannabis dried flower to anyone else, even if they have the same condition as you.

ALLERGY WARNING

Do not use if you are allergic to cannabis products.

DO NOT DRIVE OR OPERATE MACHINERY whilst taking SatiVite medicinal cannabis dried flower.

Check with your doctor when it is safe to drive after you stop taking SatiVite™ medicinal cannabis dried flower.

Things to be careful of

SatiVite™ medicinal flower cannabis dried flower may make you feel drowsy or sleepy.

Things to be mindful of

This medicine is only available with a doctor's prescription. Possession of this medication without a prescription is illegal and may lead to prosecution, fines, or both.

Side Effects

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. Please advise your doctor immediately if you experience any of the following symptoms:

Very common (affects >1 in 10 people)

- Feeling dizzy or tired

Common (affects < 1 in 10 people)

- Lack of energy or feeling weak or generally unwell.
- Problems with memory or trouble concentrating.
- Feeling abnormal or drunk.

- Feeling sleepy or drowsy
- Blurred vision
- Constipation or diarrhea
- Nausea or vomiting
- Loss of balance or falling over
- Changed sense of taste or dry mouth
- Mouth problems, including burning, pain or ulcers

Uncommon (affects <1 in 100 people)

- Stomach pain
- Sore throat or throat irritation
- Mouth or teeth changing colour

High dose THC may be associated with the following conditions:

- feeling high or feeling dissatisfied
- depression
- confusion
- hallucinations
- paranoia
- psychotic symptoms
- cognitive distortion

Short-term effects of Cannabis may include:

- altered visual and/or auditory perception
- increased appetite
- increased heart rate
- reduced blood pressure
- impaired short-term memory
- coughing, wheezing and shortness of breath
- loss of inhibition
- spontaneous laughter
- somber/reflective mood
- confusion
- reddened / bloodshot eyes
- sleepiness
- reduced co-ordination and balance

Precautions and contraindications

The risk/benefit ratio of medicinal cannabis needs to be carefully and individually considered for people who:

- Are under the age of 25 years
- Are pregnant and/or lactating
- Are at increased risk of hypotension
- Have a personal history of psychiatric disorder(s) or

family history of schizophrenia, or substance abuse.

Take special care if you drink alcohol while using SatiVite Medicinal Cannabis Dried flower. Using medicinal cannabis dried flower and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).

Other adverse effects not listed above may also occur in some patients. **Tell your doctor if you notice any other effects.**

Consumers, patients, carers and healthcare professionals are encouraged to report serious side effects (also called adverse drug events) to the Therapeutic Goods Administration (TGA) via the website **TGA online, Adverse Event Reporting** by registering and completing the report at www.tga.gov.au/reporting-problems

Do not be alarmed by this list of possible side effects as you may not experience any of them.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Storage of SatiVite™ medicinal cannabis dried flower

Storage

- Store below 25°C.
- Keep away from moisture, heat or direct sunlight.
- Keep it safe where children cannot reach it.
- Unless your doctor tells you to, do not keep medicines that you no longer need.

Once opened, if the medication is not being used within a few days, patients can take steps to ensure proper storage.

Storage options may include:

- Placing medication in a humidor (best mid-term storage), or
- Place a Boveda pack or Integra pack in the can. Where possible, it is best to avoid having these products coming contact with the dried flower, so taping these to the removable lid is an easy solution.

Expiry

The expiry date is shown on the nitro-tin can label.

Disposal

Medicines should not be disposed of via wastewater or household waste. Any unused medicine or medicine past its expiry date, as shown on the dispensing label or packaging, should be returned to the pharmacy.

Product details ingredients

Each product contains the active ingredients listed in one gram (1g) of dried flower:

EURROKA

Delta-9-tetrahydrocannabinol (THC)	290 mg
Cannabidiol (CBD)	<10mg

Instructions for administration

If you need help, please ask your pharmacist or other healthcare professional.

SatiVite™ medicinal cannabis flower may be dosed utilizing a vaporiser as follows:

- Grind flower into granules
- Loose pack granules into vaporizer chamber
- Set vaporiser temperature *
- Inhale, slow and long for full inhalation, holding inhaled breath for 3 – 5 seconds
- Wait 15 minutes to see if desired symptoms have been controlled
- If desired effects have not been achieved, repeat process increasing inhalations, until effective without causing unwanted side effects.

* Clinically indicated vaporising temperature for THC medical flower ranges from 175 Celsius to 200 Celsius. If vapor contains smoke, it is too hot and combusting.

Our sustainability commitment

Nitrogen flushed, our 100% recyclable cans keep our products fresh and help retain strong terpene aroma's which will be unveiled upon opening. Replacing the oxygen with nitrogen gas not only reduces oxidation and degradation, but it also increases the shelf-life and retains potency.

Product Sponsor

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SatiVite dried flowers are **Non-ARTG** products

References

MacCallum CA, Russo EB. Practical considerations in medical cannabis administration and dosing. Eur J Intern Med. 2018 Mar; 49:12-19. doi: 10.1016/j.ejim.2018.01.004. Epub 2018 Jan 4. Review. PubMed MID: MID: 29307505.

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