

Active Ingredient

delta-9-tetrahydrocannabinol (THC) 26% (w/w)
cannabigerol (CBG) <1% (w/w)
cannabidiol (CBD) <1% (w/w)

Consumer Medicines Information

This leaflet provides important information about using Cultiva Signature — Blue Pavé. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cultiva Signature — Blue Pavé.

Where to find information on this leaflet

- Why am I using Cultiva Signature — Blue Pavé?
- What should I know before I use Cultiva Signature — Blue Pavé?
- What if I am taking other medicines?
- How do I use Cultiva Signature — Blue Pavé?
- What should I know while using Cultiva Signature — Blue Pavé?
- Are there any side effects?
- Product details

01. Why am I using Cultiva Signature — Blue Pavé?

Cultiva Signature — Blue Pavé contains the active ingredient delta-9-tetrahydrocannabinol (THC). It also contains cannabidiol (CBD), cannabigerol (CBG) and other minor phytocannabinoids. Cultiva Signature — Blue Pavé is a whole-plant medicinal cannabis dried flower. The endocannabinoid system includes a combination of endocannabinoids, cannabinoid receptors and enzymes in the body. Cannabinoid receptors are found on the surface of cells throughout the body. Phytocannabinoids interact with the body's receptors and result in a therapeutic effect. THC activates cannabinoid receptors, particularly CB1, sending a message to the body's endocannabinoid system to start a response.

Therapeutic Class

Cannabis is a controlled drug. Possession without authority is illegal. Poison Schedule: Schedule 8.

Conditions/Symptoms

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

- Chemotherapy-induced nausea and vomiting (CINV)
- Refractory paediatric epilepsy
- Neuropathic and chronic pain
- Palliative care
- Cancer pain
- 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)
- Anxiety
- Attention-Deficit/Hyperactivity Disorder (ADHD)
- Symptom relief from autoimmune conditions

02. What should I know before using Cultiva Signature — Blue Pavé?

Warnings

- Do not use Cultiva Signature — Blue Pavé if:
- You are allergic to THC (delta-9-tetrahydrocannabinol), CBD (cannabidiol), or other minor phytocannabinoids.
 - You are less than 18 years old.
 - The use-by date printed on the packaging has expired or the package looks like it has been tampered with.
 - You have a history of drug dependence, including alcohol dependence.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you have any other medical conditions such as:

- Heart problems
- Lung problems
- Liver problems
- Epilepsy or recurrent seizures
- Panic attacks
- A family history of schizophrenia
- A history of psychosis or mood disorders
- A history of serious mental health disorders including schizophrenia or psychosis, unless specifically prescribed by a qualified healthcare professional with a knowledge of your psychiatric history.
- A family history of substance use disorder (abuse, dependence) to alcohol, opioids, stimulants, benzodiazepines, or any prescription or non-prescription substances.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Cultiva Signature — Blue Pavé is not safe to take if you are pregnant or intend to become pregnant or if you are breastfeeding or intend to breastfeed. Talk to your doctor before commencing Cultiva Blue Pavé.

Use in children

Cultiva Signature — Blue Pavé is not recommended for use in children or adolescents younger than 18 years.

03. What if I am 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 Cultiva Blue Pavé and affect how it works. Cultiva Signature — Blue Pavé may also affect how other medicines work.

Tell your doctor if you are taking medicines for:

- Sleeping problems (sleeping pills, sedatives, hypnotics e.g., pentobarbital, zopiclone, zolpidem, benzodiazepine, diphenhydramine, promethazine)
- Attention Deficit Hyperactivity Disorder (ADHD) or narcolepsy (e.g., methylphenidate, pemoline)
- Epilepsy, seizures, nerve pain (e.g., carbamazepine, phenytoin, phenobarbital)
- Pain (e.g., opioids such as codeine, morphine, oxycodone)
- Blood clotting (coumarins, e.g., warfarin)
- Cold, allergy or congestion (e.g., oxymetazoline, propylhexedrine, pseudoephedrine, antihistamine)
- Fungal infection (e.g., ketoconazole, itraconazole, fluconazole)
- Bacterial infection (e.g., erythromycin, rifampicin, clarithromycin)
- Muscular conditions like muscle spasms, overactive bladder, movement disorders (Parkinson's disease), asthma (anticholinergics: e.g., tolterodine, oxybutynin, darifenacin, solifenacin, benztropine mesylate, trihexyphenidyl, ipratropium, bromides)
- Immune conditions like rheumatoid arthritis, nephrotic syndrome, Crohn's disease, organ transplant rejection, psoriasis (cyclosporine); HIV/AIDS (ritonavir)
- Irregular heartbeat (amiodarone)
- Major depressive disorder, obsessive-compulsive disorder, premenstrual dysphoric disorder, bulimia nervosa, panic disorder (fluoxetine)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cultiva Signature — Blue Pavé.

04. How do I use Cultiva Signature — Blue Pavé?

How much to take

- Follow the directions of your doctor or pharmacist carefully.
- Your doctor will provide you with a treatment schedule based on your medical condition and needs.
- A titration period (gradually increasing the dose) is required to reach the best dose.

Cultiva Signature — Blue Pavé

- The dose and frequency of use required will vary between patients.
- Your doctor may recommend you increase the dose slowly to reach the lowest dose needed to improve your symptoms.
- Always use Cultiva Signature — Blue Pavé exactly as your doctor has prescribed.

When to take Cultiva Signature — Blue Pavé

- Cultiva Signature — Blue Pavé can be taken before or after food.
- Taking Cultiva Signature — Blue Pavé under similar conditions each day may help achieve a more consistent effect.

How to take Cultiva Signature — Blue Pavé

- Cultiva Signature — Blue Pavé should be taken as directed by your doctor.
- Cultiva Signature — Blue Pavé is available as dried medicinal cannabis flower and is designed for inhalation using a TGA-approved vapouriser.
- Use the TGA-approved vapouriser in line with the manufacturer instructions that come with it.
- Vaporisation in a TGA-approved vapouriser heats medicinal cannabis below its burning point to release the active ingredient.
- Do not use Cultiva Signature — Blue Pavé via combustion (smoking or smoking paraphernalia) as this may pose a risk to your health, including the potential to contribute to chronic obstructive pulmonary disease (COPD).

If you forget to take Cultiva Signature — Blue Pavé

- Cultiva Signature — Blue Pavé should be taken regularly at the same time each day.
- If you have trouble remembering when to use your medicine, talk to your pharmacist or doctor.
- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Speak to your doctor or pharmacist to understand when it is too close to your next dose.
- Do not take a double dose to make up for the dose you missed.

If you use too much Cultiva Signature — Blue Pavé

If you think you have used too much Cultiva Signature — Blue Pavé, you may need urgent medical attention. You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26) or,
- Contact your doctor, or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

05. What should I know while using Cultiva Signature — Blue Pavé?

Things you should do

- Take Cultiva Signature — Blue Pavé as your doctor has prescribed.
- Always use Cultiva Signature — Blue Pavé under medical supervision to help determine if the product is working or if you are having any side effects from the treatment.
- Talk to your doctor or pharmacist if you do not feel better, or if you feel worse.
- If you are starting any new medicine, remind your doctor and pharmacist that you are taking Cultiva Signature — Blue Pavé.
- Remind any doctor, pharmacist, dentist or other healthcare provider who is treating you that you are taking Cultiva Signature — Blue Pavé.
- Tell your doctor if you become pregnant while taking Cultiva Signature — Blue Pavé.
- Tell your doctor if your symptoms do not improve.

Call your doctor straight away if you:

- Are pregnant or become pregnant while taking Cultiva Signature — Blue Pavé.
- Need to have any medical tests as Cultiva Signature — Blue Pavé may affect the results of some tests.

Things you should not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not change your dose without talking to your doctor about it first.
- Do not stop taking your medicine without telling your doctor.
- If you stop taking your medicine suddenly or change the dose, your condition may worsen, or you may have unwanted side effects.
- Do not consume alcohol while you are taking Cultiva Blue Pavé. Alcohol in combination with Cultiva Blue Pavé can impair cognitive abilities, including coordination, reaction time and motor skills.
- Do not drive or operate complex machinery for 24 hours after taking Cultiva Blue Pavé.

Cultiva Signature — Blue Pavé

- Cultiva Signature — Blue Pavé is a controlled drug, and its legal status will vary between countries.
- Check if it is legal for you to take this medicine into any countries you are travelling to or through; including countries you are transiting through, and your final destinations.
- Consult with your doctor, country consulates, The Department of Foreign Affairs and Trade, insurance company and/or pharmacist to confirm if it is legal for you to travel with Cultiva Signature — Blue Pavé.

Driving or using machines

- Do not drive or operate heavy or dangerous machinery while being treated with Cultiva Signature — Blue Pavé.
- Talk to your doctor about when you can resume these activities after completing treatment.

Drinking alcohol

- Tell your doctor if you drink alcohol.
- Alcohol may increase the effects of Cultiva Signature — Blue Pavé, or the latter may increase the effects of alcohol (such as loss of balance or ability to respond quickly).

Looking after your medicine

- Store below 25°C.
- Follow the instructions in the carton on how to take care of your medicine properly.
- Store Cultiva Signature — Blue Pavé in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in a car, or on windowsills.
- Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

- If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.
- Keep out of reach of children.
- Do not use this medicine after the expiry date.

06. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary and generally as a result of first taking the medication. Please refer to the section on "How much to take". However, some side effects may need medical attention.

See the information below, and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Mental status:	General:
<ul style="list-style-type: none"> Memory impairment Difficulty concentrating Dizziness Light-headed feeling Fatigue Daytime drowsiness 	<ul style="list-style-type: none"> Headache Increased appetite Nausea Phlegm and cough Dry mouth Muscle weakness Malaise (feeling generally unwell) or a general feeling of discomfort
Eyes:	Ears:
<ul style="list-style-type: none"> Dry eyes Bloodshot eyes Altered visual perception 	<ul style="list-style-type: none"> Altered hearing perception

What to do

Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Mental status:	Brain / Nervous system:
<ul style="list-style-type: none"> Depression Thoughts of suicide Abnormal thoughts Paranoia Euphoria Seeing or hearing things that are not there Irrational thinking Hallucinations Psychosis Addiction / dependence Agitation Confusion Disorientation 	<ul style="list-style-type: none"> Numbness Burning sensation Vomiting Loss of coordination / balance Seizures or convulsions Allergy-related: <ul style="list-style-type: none"> Shortness of breath, wheezing or difficulty breathing Swelling of the face, lips, mouth, tongue, or throat which may cause difficulty breathing Rash, hives, itching, redness, swelling blistering or peeling of the skin

Heart and Circulation:

- Rapid or irregular heartbeat
- Chest pain
- Signs of low blood pressure such as feeling faint, light-headed, dizziness

What to do

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people.

Reporting Side Effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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

07. Product Details

This medicine's name is Cultiva Signature — Blue Pavé, and it is only available with a doctor's prescription.

What Cultiva Signature — Blue Pavé contains

Active ingredient(s) (Main ingredient(s))	Whole dried cannabis indica-dominant flower delta-9-tetrahydrocannabinol (26% THC) Cannabigerol (<1% CBG) Cannabidiol (<1% CBD)
Other ingredient(s) (inactive ingredient(s))	Whole dried cannabis indica-dominant delta-9-tetrahydrocannabinol (26% THC) Cannabigerol (<1% CBG) Cannabidiol (<1% CBD)

Cannabis contains over 70 different cannabinoids and other naturally occurring compounds. Do not take this medicine if you are allergic to any of these ingredients.

What Cultiva Signature — Blue Pavé looks like

Cultiva Signature — Blue Pavé features dense, trichome-rich buds with deep green tones, rich purple highlights, and bright orange pistils.

Who distributes Cultiva Signature — Blue Pavé?

Nectar Portfolio Pty Ltd
6 Luton Lane, Hawthorn, VIC 3122, Australia
products@nectarbrands.com.au Ph: 1300 140 160

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