# sundaze Callisto Dried Cannabis

# Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the <u>full CMI</u> for further details.

# 1. Why am I using sundaze Callisto?

sundaze Callisto contains the active ingredients delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). sundaze Callisto is not approved for any specific indication and should only be used to treat specific conditions or symptoms authorised by your doctor.

For more information, see Section 1. Why am I using sundaze Callisto? in the full CMI.

### 2. What should I know before I use sundaze Callisto?

Do not use if you have ever had an allergic reaction to sundaze Callisto or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use sundaze Callisto? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with sundaze Callisto and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

### 4. How do I use sundaze Callisto?

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained within this leaflet.
- If you do not understand the instruction on the pharmacist dispensing label, ask your doctor or pharmacist for help.
- A titration period is required to reach optimal dose. The volume, number and timing of doses will vary between
  patients. Your doctor will provide you with a treatment schedule based on your needs. Always use sundaze
  Callisto exactly as your doctor has told you.
- sundaze Callisto can be taken before or after food.
- Only a doctor can start you on treatment with sundaze Callisto. Your doctor will assess you from time to time to see if you should continue taking sundaze Callisto.

More instructions can be found in Section 4. How do I use sundaze Callisto? in the full CMI.

# 5. What should I know while using sundaze Callisto?

# Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using sundaze Callisto.
- You must tell your doctor if you have or have had any allergies to cannabis or cannabis-based medicines.
- You must tell your doctor if you have or have had any problem with your liver, kidneys, heart, gut, substance use disorder (abuse, dependence), or any other medical condition.
- Tell your doctor if you have or have had any psychotic or concurrent disorder.
- Tell your doctor if you are under 18 years of age.
- Tell your doctor if you are pregnant or planning to become pregnant. Tell your doctor if you become pregnant while taking sundaze Callisto.
- Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.
- Take sundaze Callisto as your doctor has prescribed.
- If you are about to start any new medicine, tell your doctor and pharmacist that you are taking sundaze Callisto.
- Tell your doctor if your symptoms do not improve.
- If you need to have any medical tests while you are taking sundaze Callisto, tell your doctor.

Things you should not do	<ul> <li>Do not stop using this medicine suddenly (if relevant).</li> <li>Do not take sundaze Callisto if you have an allergy to cannabis or cannabis-based medications.</li> <li>Do not take sundaze Callisto after the use-by (expiry) date printed on the packaging or if the packaging shows signs of tampering.</li> <li>Do not take sundaze Callisto if you are pregnant, planning to become pregnant, or breastfeeding.</li> <li>Do not take this medicine to treat any other complaint unless your doctor says it is safe.</li> <li>Do not give this medicine to anyone else, even if they have the same condition as you.</li> </ul>
Driving or using machines	Do not drive or operate machinery while taking sundaze Callisto.
Drinking alcohol	<ul> <li>Take special care if you drink alcohol while taking this medicine.</li> <li>Taking sundaze Callisto and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).</li> </ul>
Looking after your medicine	<ul> <li>Keep your sundaze Callisto in its packaging until it is time to take it.</li> <li>If you leave this medicine out of its packaging, it may not keep well.</li> <li>Store it in a cool dry place away from moisture, heat or sunlight.</li> <li>Do not store sundaze Callisto or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.</li> <li>Keep sundaze Callisto where children cannot see it or reach it.</li> </ul>

For more information, see Section 5. What should I know while using sundaze Callisto? in the full CMI.

# 6. 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. However, some side effects may need medical attention. You are more likely to get side effects when you start your treatment. They are usually mild and wear off within a few hours.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- daytime drowsiness
- fatigue
- dry eyes
- increased appetite
- nausea

- dizziness
- dry mouth
- headache
- difficulty concentrating
- · memory impairment
- blurred vision
- constipation or diarrhoea
- euphoria

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if any of the following happen:

- · thoughts of suicide
- · rapid heartbeat
- chest pain
- convulsion
- hallucinations
- psychosis
- you develop signs of allergy such as swelling of the face, lips, mouth, tongue, throat or other part of the body; shortness of breath or difficulty breathing; rash, itching or redness on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side-effects you may get. You can report side effects to your doctor, or directly on 1800 844 920 or via orders@montu.com.au.

# sundaze Callisto Dried Cannabis

Active ingredient(s): delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using sundaze Callisto. 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 sundaze Callisto.

#### Where to find information in this leaflet:

- 1. Why am I using sundaze Callisto?
- 2. What should I know before I use sundaze Callisto?
- 3. What if I am taking other medicines?
- 4. How do I use sundaze Callisto?
- 5. What should I know while using sundaze Callisto?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using sundaze Callisto?

sundaze Callisto contains the active ingredients delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

sundaze Callisto is not approved for any specific indication and should only be used to treat specific conditions or symptoms prescribed by your doctor.

sundaze Callisto may be used to:

- Relieve chronic non-cancer pain
- Relieve cancer related pain
- Improve sleep (insomnia)
- Decrease inflammation
- Reduce tremors
- Provide relief from nausea
- Reduce spasticity from neurological conditions
- Stimulate appetite in anorexia or wasting conditions associated with chronic illness.

Your doctor may prescribe sundaze Callisto for another purpose.

Ask your doctor if you have any questions about why sundaze Callisto has been prescribed for you.

sundaze Callisto is an alternative therapeutic option when medicines and lifestyle treatments have

not been beneficial. The therapeutic benefit of sundaze Callisto may vary between individuals.

This medicine is only available with a doctor's prescription.

# 2. What should I know before I use sundaze Callisto?

# Warnings

#### Do not use sundaze Callisto if:

- you are allergic to cannabis, cannabis-based medications, or any of the ingredients listed at the end of this leaflet.
- You are pregnant, planning to become pregnant, or breastfeeding. THC can pass into your breastmilk if you are breastfeeding. It may affect your baby.

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:
  - allergies to any other medicines
  - any problem with your liver
  - any problems with your kidney
  - any problems with your heart
  - gastrointestinal obstruction
  - any previous psychotic or concurrent disorder
  - any other medical conditions
  - take any medicines for any other condition
  - substance use disorder (abuse, dependence) to alcohol, opioids, benzodiazepines, or illicit stimulants.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

#### 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.

# 3. 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.

You should also tell any health professional who is prescribing a new medication for you that you are taking sundaze Callisto.

If you see a different doctor or go into hospital, let them know all the medicines you are taking.

# Some medicines may interfere with sundaze Callisto and affect how it works.

Avoid taking sundaze Callisto with alcohol and/or other CNS depressants/sedatives including prescription medications, e.g., benzodiazepines. Using sundaze Callisto at the same time as alcohol and/or other sedative drugs may cause more severe levels of impairment and adverse effects.

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

# 4. How do I use sundaze Callisto?

#### How much to take/use

- Follow all directions given to you by your doctor.
- They may differ to the instructions in this leaflet.
- If you do not understand the instruction on the label, ask your doctor or pharmacist for help.
- A titration period is required to reach optimal dose. The number and timing of doses will vary between individuals. Your doctor will provide you with a treatment schedule based on your needs. Always use sundaze Callisto exactly as your doctor has told you.
- Only a doctor can start you on treatment with sundaze Callisto. Your doctor will assess you from time to time to see if you should continue taking sundaze Callisto.
- Your doctor may increase your dosage until a dose is reached which works best for you.
- Note that higher doses of sundaze Callisto are associated with an increased risk of experiencing side effects.
- Follow the instructions provided and use sundaze Callisto until your doctor tells you to stop.

## When to take / use sundaze Callisto

- sundaze Callisto should be used as directed by your doctor.
- sundaze Callisto can be taken before or after food.

### How to use sundaze Callisto

- This product should be administered using a medical device vaporizer, as recommended by your doctor or pharmacist.
- Your dose of sundaze Callisto is individualized, and the rate and speed of dose adjustment is dependent on each individual response. It is recommended to start low and titrate the dose slowly. The optimal dose is the lowest dose that achieves the highest benefit.
- Follow the instructions provided and use sundaze Callisto until your doctor tells you to stop.
- If you have any further questions on the use of sundaze Callisto, ask your doctor or pharmacist.

# If you forget to use sundaze Callisto

sundaze Callisto should be used regularly at the same time each day. If you have trouble remembering when to use your medicine, talk to your doctor or pharmacist.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

# If you use too much sundaze Callisto

If you think that you have used too much sundaze Callisto, 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.

# 5. What should I know while using sundaze Callisto?

### Things you should do

- Take sundaze Callisto as your doctor has prescribed.
- If you are about to start any new medicine, remind your doctor and pharmacist that you are taking sundaze Callisto.
- Take special care if you drink alcohol while using sundaze Callisto. Using sundaze Callisto and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).

### Call your doctor straight away if you:

- Are pregnant or become pregnant while taking sundaze Callisto.
- Need to have medical tests while you are taking sundaze Callisto. It may affect the results of some tests
- Tell your doctor if your symptoms do not improve.

Remind any doctor, dentist, or pharmacist you visit that you are using sundaze Callisto.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor. If you stop taking it suddenly or change the dose, your condition may worsen, or you may have unwanted side effects.
- Do not use sundaze Callisto to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

# Travelling overseas with sundaze Callisto

Check that it is legal for you to take sundaze
 Callisto into any countries you are travelling to
 and countries you are travelling through. sundaze
 Callisto is a Controlled Drug in Australia, and its
 legal status will vary between countries.

# **Driving or using machines**

Do not drive or use machinery while taking sundaze Callisto.

sundaze Callisto may cause dizziness or drowsiness in some people.

# **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

Alcohol may increase the effects of sundaze Callisto, or the latter may increase the effects of alcohol (such as loss of balance or ability to respond quickly).

## Looking after your medicine

- Keep your sundaze Callisto in its packaging until it is time to take it.
- If you leave sundaze Callisto out of its packaging, it may not keep well.

Follow the instructions provided on the label on how to take care of your medicine properly.

Store it 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 the car or on windowsills.

A cupboard at least one and a half meters above the ground is a good place to store medicines.

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.

Do not use this medicine after the expiry date.

# 6. 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. 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

Less serious side effects	What to do
<ul> <li>daytime drowsiness</li> <li>dizziness</li> <li>fatigue</li> <li>dry mouth</li> <li>dry eyes</li> <li>headache</li> <li>increased appetite</li> <li>difficulty concentrating</li> <li>nausea</li> <li>memory impairment</li> <li>blurred vision</li> <li>constipation or diarrhoea</li> <li>euphoria</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
Allergy-related:  • swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in breathing  • shortness of breath or difficulty in breathing  • skin reaction which may include rash, itching, redness, blistering or peeling of the skin	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of
<ul><li>Cardiovascular:</li><li>rapid heartbeat</li><li>chest pain</li><li>low blood pressure/feeling faint</li></ul>	these serious side effects.
Brain/Nervous system:  convulsions numbness burning sensation vomiting loss of coordination balance disorientation confusion depression agitation hallucinations psychosis thoughts of suicide  General:	
<ul><li>upper respiratory infection</li><li>strong abdominal pain</li></ul>	

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 sideeffects you experience, you can report side effects on 1800 844 920 or via <a href="mailto:orders@montu.com.au">orders@montu.com.au</a>. 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.

# 7. Product details

This medicine is only available with a doctor's prescription.

#### What sundaze Callisto contains

Active ingredient (main ingredient)	delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD)
	Contains 22% w/w THC and not more than 1% w/w CBD
Other ingredients	None
(inactive ingredients)	

Do not take this medicine if you are allergic to any of these ingredients.

### What sundaze Callisto looks like

sundaze Callisto is a whole cannabis dried flower presented in a plastic jar. Each jar contains 10 grams of dried cannabis.

#### Who distributes sundaze Callisto

sundaze Callisto is supplied in Australia by:

Montu Group Pty Ltd

Telephone: 1800 844 920 Email: orders@montu.com.au Website: www.montu.com.au

This leaflet was prepared in January 2023.