



Store below 25C away from light. Keep out of reach of children. Tamper Evident. Do not use if safety seals are broken.

### **Inactive Ingredients on Leaflet (Page 2)**

Water, modified vegetable oil, glycerol, citric acid, potassium sorbate, sucralose, peppermint oil

### **Section 8 of Leaflet**

#### **What it looks like**

NanoCBD is provided as a dark-amber liquid in a white 30 mL plastic spray container and a pump. The pump is protected with a plastic cap. NanoCelle is a novel drug delivery system that enables very small particles to be delivered as an oral spray. The Nanocelle spray contains submicron size particles with a fat-soluble core containing the drug, and a water-soluble outer layer.

NanoCBD is a mouth spray (oro-buccal spray) which contains the active ingredient cannabidiol.

## 5. While taking NanoCBD™

### Things you must do:

- If you are about to start on any new medicine tell your doctor that you are taking NanoCBD™.
- Take special care if you drink alcohol while using NanoCBD™. Taking NanoCBD™ and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).
- Talk to your doctor before using this medicine if you are pregnant or plan to become pregnant.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

### Things you must not do:

- Do not give NanoCBD™ to anyone else, this medicine is prescribed for you. Even if they have the same condition as you, do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Do not use NanoCBD™ while breastfeeding or during pregnancy, unless advised by your doctor.

### Things to be careful of:

Taking NanoCBD™ with food and drink

- Take special care if you drink alcohol while using NanoCBD™. Using NanoCBD™ and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).
- You can take NanoCBD™ with or without food.

Driving and using machines

- You must not drive or use machinery when you are taking NanoCBD™.

Foreign travel with NanoCBD™

- Check that it is legal for you to take this medicine into any countries you are travelling to and countries you are travelling through. NanoCBD™ is a controlled drug and its legal status will vary between countries.

## 6. Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well as a result of taking NanoCBD™.

All medicines can have side effects. The severity of these symptoms may vary and may require medical treatment.

You are more likely to experience side effects when you start your treatment. They are usually mild and will subside within a few hours.

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

### Tell your doctor if you notice any of the following side effects

#### Very common (affecting more than 1 in 10 people)

- Feeling dizzy or tired
- Feeling hungry
- Problems with your memory or having trouble concentrating
- Changed sense of taste or a dry mouth
- Experiencing low blood pressure

#### Common (affecting less than 1 in 10 people)

- Lack of energy or feeling weak or generally unwell
- Problems with your memory or having trouble concentrating
- Feeling abnormal or drunk
- Feeling sleepy or drowsy
- Blurred vision
- Constipation or diarrhoea
- Feeling nauseous or vomiting
- Loss of balance or falling over
- Mouth problems, including burning, pain or mouth ulcers
- Feeling depressed or disorientated
- Feeling over-excited or losing touch with reality
- Difficulty speaking
- Seeing or hearing things that are not there (hallucinations)

#### Uncommon (affecting less than 1 in 100 people)

- Stomach pain
- Sore throat or throat irritation
- Mouth or teeth changing colour
- Irritation where NanoCBD™ is sprayed
- Red and swollen mouth or peeling inside the mouth
- Delusional thoughts
- Paranoid thoughts / feeling that other people are against you
- Fast or irregular heartbeats, also called palpitations
- Fainting

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

- Thoughts of suicide
- You develop signs of allergy such as swelling of the face, lips, tongue or other part of the body; severe dizziness or fainting; redness, itching or rash on the skin.

### Tell your doctor if you notice anything else that is making you feel unwell.

Some people may experience other side effects not yet known or mentioned in this leaflet. Some side effects may only be apparent when your doctor assesses you from time to time.

## 7. After taking NanoCBD™

### Storage

- Do not use NanoCBD™ after the expiry date shown on the product packaging.
- Store NanoCBD™ upright in its carton below 25°C. Keep away from heat and direct sunlight.
- Do not use NanoCBD™ after it has been open for 60 days.
- Unless your doctor tells you to, do not keep medicines that you no longer need.
- Keep out of reach and sight of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### 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.

## 8. Product description

### What it looks like

NanoCBD™ is provided as a dark-amber liquid in a white 30 mL plastic spray container and a pump. The pump is protected with a plastic cap.

NanoCelle™ is a novel drug delivery system that enables very small particles to be delivered as an oral spray. The NanoCelle™ spray contains sub-micron size particles with a fat-soluble core containing the drug, and a water-soluble outer layer.

NanoCBD™ is a mouth spray (oro-buccal spray) which contains the active ingredient cannabidiol.

The active ingredient is 16.67 mg/ml cannabidiol (CBD).

Inactive ingredients:

Water, Modified vegetable oil, Glycerol, Citric acid, Potassium sorbate, Sucralose, Peppermint oil

**It is strongly recommended that you keep a copy of your doctor's business card on your person at ALL times.**

## 9. Sponsor details

NanoCBD™ is supplied in Australia by:  
**Medlab Clinical Limited™**  
 66 McCauley Street  
 Alexandria NSW 2015  
 Toll free: 1300 369 570

NanoCBD™ is a registered trademark of Medlab Clinical Limited™, Australia.  
 NanoCBD™ is a Non-ARTG product.

## 10. Date of preparation

This leaflet was prepared in Feb 2020. Version 1.0

Active Ingredient (per 2 sprays - 300 microlitres) Cannabidiol (CBD) 5 mg

Directions for use: Take as prescribed by your doctor.

Company: medlab.co  
File Name: FINAL NanoCBD AUS 30mL Label  
Dimensions: 38.1 mm x 88.9mm (1.5" x 3.5")  
Scale: 100% (if printed on A4 sheet)  
Date: 29/08/2019  
Colours:



**NB.** Items in PMS 690 not to be printed (1 x instance - dieline)

medlab.		
<b>ACTIVE INGREDIENTS:</b> (per 2 sprays - 300 microlitres) Cannabidiol (CBD) 5 mg	<b>CONTROLLED DRUG</b> <small>POSSESSION WITHOUT AUTHORITY ILLEGAL KEEP OUT OF REACH OF CHILDREN</small>	<b>DIRECTIONS FOR USE:</b> Take as prescribed by your doctor.
<b>WARNINGS:</b> Do not overdose. Contains potassium sorbate. May cause drowsiness. Do not drive a vehicle or operate machinery. Avoid alcohol.  Store below 25°C away from light.	<b>NanoCBD™</b> Hemp Oil Extract 16.67 mg/ml of CBD  <small>PRODUCT OF THE UNITED STATES</small> 30 mL Buccal Spray	<b>INDICATIONS FOR USE:</b> As prescribed by your health professional.  <b>Always read the CMI.</b> Medlab Clinical Ltd 66 McCaulley Street Alexandria NSW 2015

## How to take NanoCBD (page 1 Leaflet)

## NanoCBD™

### Hemp oil extract (16.67 mg/mL cannabidiol)

Oro-buccal Spray 30 mL

#### 1. What is in the leaflet?

This leaflet answers some common questions about NanoCBD™. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. Those updates may contain important information about the medicine and its use, of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NanoCBD™ against the benefits they expect it will have for you.

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

Keep this leaflet. You may need to read it again.

#### 2. What NanoCBD™ is used for?

NanoCBD™ is used:

- to reduce anxiety and depression
- to improve episodes of schizophrenia
- to reduce cancer treatment associated nausea and vomiting
- to improve appetite
- to reduce pain and inflammation due arthritis
- to reduce seizures in epilepsy patients.

Your doctor may prescribe NanoCBD™ for another purpose.

Ask your doctor if you have any questions about why NanoCBD™ has been prescribed for you.

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

#### 3. Before you take NanoCBD™

##### Do not use NanoCBD™ if:

- You are allergic (hypersensitive) to cannabis extracts or any of the other ingredients of NanoCBD™ listed in Section 8.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- You are breastfeeding.

Do not use NanoCBD™ during pregnancy, unless advised to by your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

Do not use this medicine if any of the above applies to you.

If you are not sure whether you should start using NanoCBD™, talk to your doctor.

##### Tell your doctor if:

- You are pregnant or plan to become pregnant.
- You are under 18 years of age.
- You have epilepsy or regular fits (seizures).
- You have liver or kidney problems.
- You 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.
- You are elderly, especially if you have problems doing everyday activities such as making hot food and drinks.
- You have previously taken any drug or substance recreationally.

If you have not told your doctor about any of the above, tell them before you start using NanoCBD™.

##### Taking other medicines:

Inform your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also inform any health professional who is prescribing a new medication for you that you are taking NanoCBD™.

Some medicines may interfere with NanoCBD™.

If any of the above apply to you (or you are not sure), consult your doctor or pharmacist before using NanoCBD™.

If you start seeing a different doctor or medical facility such as a hospital, let them know all the medicines you are using.

#### 4. How to take NanoCBD™

A titration period is required to reach optimal dose. The number and timing of sprays will vary between patients. Your doctor will provide you with a treatment schedule based on your needs. Always use NanoCBD™ exactly as your doctor has told you.

NanoCBD™ can be taken before or after food.

Only a doctor can start you on treatment with NanoCBD™. Your doctor will assess you from time to time to see if you should continue taking it.

##### Using the spray:

1. Only use NanoCBD™ in your mouth – on the inside of your cheek.
2. Hold the spray between your thumb and second finger. Put your first finger on the nozzle.
3. Hold it upright and point into your mouth. Point the nozzle towards the inside of your cheek. Alternate the sites where you spray each time.

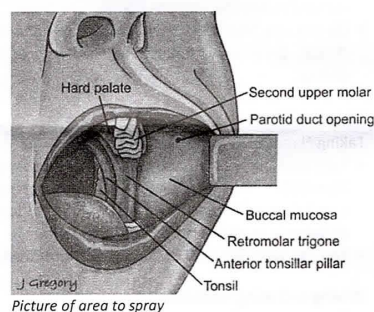
4. Press the nozzle down firmly. Do not take more sprays as directed by your doctor, even if you feel that only a small amount of spray was dispensed from the nozzle.

5. If you need to apply more than two sprays at a time, wait 15 seconds before administering the next two sprays.

6. Replace the protective cap.

In case of contact with eyes, rinse immediately with water, and contact your doctor.

- Do not inhale in the spray.
- Do not spray near children or pets.



##### How long to use it:

Continue to use this medicine for as long as your doctor tells you to.

Dependence on NanoCBD™ is unlikely.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

##### If you forget to use it:

Do not increase dosage frequency or quantity to make up for a missed spray.

If you have trouble remembering when to use your medicine, talk to your pharmacist or doctor.

##### If you use too much (overdose):

Immediately contact your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much NanoCBD™.

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

If you accidentally use more of this medicine than prescribed, you may:

- See or hear things that are not there (hallucinations).
- Feel dizzy, sleepy or confused.
- Feel your heart rate change.

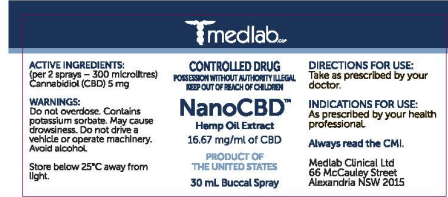
If you experience any of the above symptoms, and they become concerning to you, tell your doctor or pharmacist.



Company: medlab.co  
 File Name: FINAL NanoCBD AUS 30mL Label  
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 Date: 29/08/2019  
 Colours:



**NB.** items in PMS 690 not to be printed (1 x instance - dieline)



See Final NanoCBD AUS 30mL Label Image.

## NANOCDB

none solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70658-122
<b>Route of Administration</b>	BUCCAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CANNABIDIOL (UNII: 19GBJ60SN5) (CANNABIDIOL - UNII:19GBJ60SN5)	CANNABIDIOL	1.938 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	77.27 g in 100 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.096 g in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	4.41 g in 100 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 g in 100 mL
REBAUDIOSIDE A (UNII: B3FUD0528F)	

PEPPERMINT OIL (UNII: AV092KU4JH)	0.31 g in 100 mL
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	15.65 g in 100 mL

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70658-122-12	1 in 1 CARTON	04/21/2020	
1		30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		04/21/2020	

**Labeler** - Creative Essences Inc (079120182)

**Registrant** - Creative Essences Inc (079120182)

### Establishment

Name	Address	ID/FEI	Business Operations
Creative Essences Inc		079120182	manufacture(70658-122)