

NanaBis™

Cannabis sativa L. / *Cannabis indica* L. extract (delta-9-tetrahydrocannabinol and cannabidiol)

Oromucosal Spray 15 mL

1. What is in the leaflet?

This leaflet answers some common questions about NanaBis™.

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 NanaBis™ against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

2. What NanaBis™ is used for

Cancer pain is mostly disease related. Also, the chronic treatment-related pain syndromes are persistent painful complications of a cancer.

NanaBis™ is used to improve symptoms related to intractable pain in cancer patients.

Insufficient management of cancer-associated chronic and neuropathic pain adversely affects patient quality of life. Patients who do not respond well to opioid analgesics, or have severe side effects from the use of traditional analgesics are in need of alternative therapeutic options. NanaBis™ is used as an alternative or as an adjuvant to opioid analgesics.

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.

This novel technology has advantages for drugs that are poorly absorbed by the body. This includes a better absorption and availability and the reduction of side effects.

NanaBis™ is a mouth spray (oro-buccal spray) which contains the active ingredients delta-9-tetrahydrocannabinol and cannabidiol.

Your doctor may prescribe NanaBis™ for another purpose.

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

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

Dependence on NanaBis™ is unlikely.

3. Before you take NanaBis™

Do not use NanaBis™ if:

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

Some of the 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 or anyone directly related to you has any mental health problems such as schizophrenia, psychosis or other significant psychiatric disorder.
- You are breast-feeding.
- Do not use NanaBis™ 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 NanaBis™, 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 heart beat.
- You are elderly, especially if you have problems doing everyday activities such as making hot food and drinks.
- You have previously abused any drug or substance.

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

Important information about some of the ingredients of NanaBis™

Taking other medicines

Tell 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 tell any health professional who is prescribing a new medication for you that you are taking NanaBis™.

Some medicines may interfere with NanaBis™.

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

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

4. How to take NanaBis™

Always use NanaBis™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Only use NanaBis™ in your mouth – on the inside of your cheek.

You can use NanaBis™ with or without food.

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

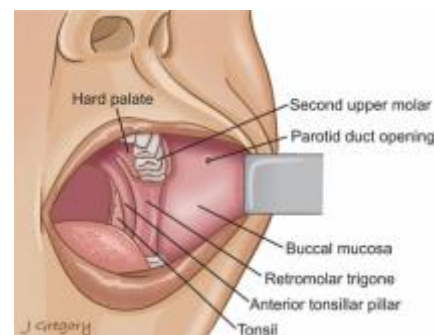
Using your spray

1. Hold the spray between your thumb and second finger. Put your first finger on the nozzle.
2. Hold it upright and point into your mouth. Point the nozzle onto the inside of your cheek. Alternate the sites where you spray each time.
3. Press the nozzle down firmly. Do not take more than one spray at a time, even if you feel that you only got a small amount of spray.
4. Replace the protective cap.

If you get spray in your eyes by accident, wash them as soon as possible with water.

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

Picture of area to spray



How long to use it

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

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 dose at the same time 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)

Australian patients:

Immediately telephone 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 NanaBis™.

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 get any of the above and they get serious, please tell your doctor or pharmacist.

5. While you are taking NanaBis™

Things you must do

- If you are about to be started on any new medicine tell your doctor that you are taking NanaBis™.
- Take special care if you drink alcohol while using NanaBis™. Using NanaBis™ 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.
- Whether male or female you must use a reliable contraceptive method while using this medicine. Keep doing this for at least 3 months after your treatment has stopped.
- 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 NanaBis™ 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 NanaBis™ while breast-feeding / do not use NanaBis™ during pregnancy, unless advised to by your doctor.

Things to be careful of

Using NanaBis™ with food and drink

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

Driving and using machines

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

Foreign travel with NanaBis™

- Check that it is legal for you to take this medicine into any countries you are travelling to and countries you are travelling through. NanaBis™ 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 while you are using NanaBis™.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment.

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

Very Common (affecting more than 1 in 10 people)

- feeling dizzy or tired

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 or being sick
- loss of balance or falling over
- changed sense of taste or a dry mouth
- mouth problems, including burning, pain or mouth ulcers
- feeling depressed or disorientated
- feeling over-excited or losing touch with reality
- difficulty speaking
- eating more or less than usual
- seeing or hearing things that are not there (hallucinations)

Uncommon (affecting less than 1 in 100 people)

- tummy pain
- sore throat or throat irritation
- mouth or teeth changing colour
- irritation where NanaBis™ is sprayed
- red and swollen mouth or peeling inside it
- believing ideas that are not true
- feeling that other people are against you
- fast or irregular heartbeats, also called palpitations
- fainting

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

- 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 have other side effects not yet known or mentioned in this leaflet. Some side effects may only be found when your doctor does tests from time to time.

7. After taking NanaBis™

Storage

- Do not use NanaBis™ after the expiry date shown on the product packaging.
 - Store unopened NanaBis™ upright in its carton between 15°C to 30°C.
 - Store opened NanaBis™ in an upright position below 25°C. Keep away from heat and direct sunlight.
 - Do not use NanaBis™ after it has been open for 60 days (15 mL).
 - Unless your doctor tells you to, do not keep medicines that you no longer need.
- Keep out of the 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

NanaBis™ is provided as a dark-amber liquid in a white 15 mL plastic spray container and a pump. The pump is protected with a plastic cap. NanaBis™ is packed as multi spray container in each carton.

The active substances are cannabis extracts. Each millilitre (mL) contains 8.67 mg/mL delta-9-tetrahydrocannabinol (THC) and 8 mg/mL cannabidiol (CBD). Each 300 microlitre spray contains 2.6 mg THC and 2.4 mg CBD.

Excipient ingredients:

Water-purified
Modified vegetable oil
Glycerol
Citric acid
Potassium sorbate
Stevia
Peppermint oil

NanaBis™ Mediband:

Inside of the carton you find a Mediband containing information about the NanaBis™ product and emergency contact details. Mediband provide peace of mind, so when the unexpected happens, critical medical information will be conveyed quickly.

The band is made of medical-grade silicon, is hard-wearing and non-toxic.

Replacement Medibands are available by contacting the Sponsor.

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

9. Sponsor details

NanaBis™ is supplied in Australia by:

Medlab Clinical Limited™
66 McCauley Street
Alexandria NSW 2015
Toll free: 1300 369 570

NanaBis™ is registered trade mark of Medlab Clinical Limited™, Australia

NanaBis™ is a Non-ARTG product.

10. Date of preparation

This Leaflet was prepared in Oct 2017. Version 3.0