



Bedica THC 2,0% oil, 10 ml
Bedrocan THC 2,0% oil, 10 ml
Bediol CBD 2,0% / THC 1,3% oil, 10 ml
Bedrolite CBD 2,0% oil 10 ml
Bedrolite CBD 10% oil, 10 ml
For sublingual use.

Page 1 of 5
Revision: 1
Translated by: SZ

Please read all of this leaflet carefully before you start using medicinal cannabis oil, because it contains important information for you.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your Transvaal Apotheek pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet in section 5, please inform the pharmacist.

What is in this leaflet?

1. What is medicinal cannabis?
2. What is medicinal cannabis used for?
3. When should you not use medicinal cannabis oil or is extra caution required?
4. How do I use medicinal cannabis oil?
5. What are the possible side effects?
6. Can I use cannabis oil with my other medicines?
7. How do I store medicinal cannabis oil?
8. Contents of the pack and other information.
9. Dosing cannabis oil.

1. What is medicinal cannabis?

Cannabis consists of the dried flowers of the pistillate (female) plant of the Cannabis sativa L. This is subdivided into the species of cannabis sativa and cannabis indica. Other names for cannabis include marijuana or weed. Cannabis contains several active ingredients, such as dronabinol (THC) and cannabidiol (CBD). THC is usually the main ingredient, although other substances like CBD can also contribute to the efficacy. Cannabis provided by the pharmacy meets the highest quality standards and is merely meant for medical purposes. Therefore we speak of medicinal cannabis.

2. What is medicinal cannabis used for?

There are different varieties of medicinal cannabis, these differ in composition, potency and mode of action. Five different oils have been developed, the choice for the most suitable oil depends on your symptoms and the indication for use. Together with you doctor, your pharmacist decides which oil is most suitable for you.

The doctor prescribes medicinal cannabis when conventional treatments and medicines do not adequately help or cause too many side effects.

Bediol CBD 2,0% / THC 1,3% oil, 10 ml and Bedrolite CBD 2,0% oil, 10 ml

There are indications that cannabis with high levels of CBD and THC (such as Bediol CBD 2.0% / THC 1.3% oil) works well against pain and spasms, for example in multiple sclerosis patients. Due to the possible anti-inflammatory properties of CBD, this oil may also produce better effects than the other oils in conditions associated with inflammatory reactions. In chronic nerve pains, patients often start with Bediol CBD 2.0% / THC 1.3% oil, and in case of insufficient pain relief, one switches to another variety.

Bedica THC 2,0% oil, 10 ml and Bedrocan THC 2,0% oil, 10 ml

Cannabis with predominantly THC is preferred in conditions such as the Gilles de la Tourette's syndrome, therapy resistant glaucoma and with symptoms such as weight loss, nausea and vomiting. The Bedica THC 2.0% oil is a cannabis of the indica species. In addition to the known effects of cannabis, such as pain reduction, it has an extra strong relaxing effect on the body and mind. This can be a suitable choice for patients who experience agitation or spasms. The Bedrocan THC 2.0% oil is a cannabis of the sativa species. Like the Bedica, it has the known effects of cannabis, such as pain relief.

Bedrolite CBD 10% oil, 10 ml

The Bedrolite CBD 10% oil is used in the treatment of epilepsy. This cannabis oil contains less than 1% THC. The unwanted effects of THC (getting 'high') are therefore not present. This oil is therefore also suitable for use in children.

Is there evidence for the efficacy?

There is sufficient scientific data available to demonstrate that cannabis is effective in: pain, muscle cramps and muscle cramps in MS or spinal cord injury; Nausea, decreased appetite, weight loss and weakening due to cancer and AIDS; Nausea and vomiting due to medication or radiation in cancer, hepatitis C or HIV infection and AIDS; Chronic pain (mainly when the cause is related to the nervous system, for example due to damage of a nerve tract, phantom pain, facial pain or chronic pain that persists after treatment of shingles); Gilles de la Tourette's syndrome; Therapy resistant glaucoma.

In addition, more and more data and positive reports from patients and doctors are available on the efficacy of cannabis in other conditions. However, the scientific evidence for these cases is insufficient. Examples of this include Crohn's disease, ulcerative colitis, epilepsy, itching, migraine, rheumatism, rheumatoid arthritis, ADHD and brain trauma (for more information, see also www.cannabis-med.org). Medical cannabis does not play a role in the cure of the conditions, but it can reduce the



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symptoms of the diseases. Also, cannabis can help reduce the dose and/or side effects of other medications.

3. When should you not use medicinal cannabis oil or is extra caution required?

When can you not use medicinal cannabis?

You may not use medicinal cannabis if you have suspected congenital long QT-syndrome and if you are predisposed to psychotic disorders. Medicinal cannabis must be avoided in Brugada syndrome, because it can lead to an abnormal ECG. Caution is advised in patients with other psychiatric problems, cardiac arrhythmias, angina pectoris and ischemic heart disease. Caution is advised in case of glaucoma.

Medicinal cannabis oil contains refined arachis oil. Arachis oil, also known as peanut oil, is a vegetable oil derived from peanuts. Refined arachis oil is purified from peanut proteins and, in contrast to raw arachis oil, can be used by people with a peanut allergy. Crude arachis oil can cause mild allergic reactions in some individuals with peanut allergy and should be avoided.

When should you be extra cautious?

Can I use this medicine if I'm pregnant, breast-feeding or are planning to have a baby?

Pregnancy: Do NOT use this medicine if you are pregnant or want to become pregnant soon. The active ingredients of cannabis can reach the unborn child through the blood. Some children whose mother has used cannabis during pregnancy have stunted growth, sleeping problems, are hyperactive or suffer from concentration problems.

Breastfeeding: Do NOT use this medicine if you are breastfeeding or stop breastfeeding. Active ingredients of cannabis such as dronabinol (THC) enter the breast milk and may then cause adverse effects in the baby.

Food and drinks?

You can eat everything. Avoid drinking grapefruit juice. The absorption of the active substances can be influenced by it. For quick admission into the bloodstream, you should drip the cannabis oil under the tongue. The taste can be neutralized by eating olives or a piece of banana after dripping under the tongue. The bitter taste can vary per bottle.

Drinking alcohol? Alcohol and cannabis reinforce and significantly enhance each other's action. Therefore, limit the use of alcohol and preferably do not drink it. Absolutely do not drive a car if you have been drinking alcohol while using cannabis.

Driving?

In the Netherlands, as of July 1, 2017, it is forbidden by law for users of cannabis to participate actively in traffic, even if there is a medical need. This prohibition does not apply to users of cannabis oil containing only CBD (this is only the Bedrolite CBD oil). For users of Bediol, Bedica and/or Bedrocan, it is prohibited by law to drive a car, regardless of the dosage used.

Traveling

Medicinal cannabis oil is covered by the Opium Act. In many countries, the possession and use of drugs that fall under the Opium Act are strictly prohibited. If you are traveling and want to take your medicinal cannabis oil with you, you must apply for an official declaration. Traveling abroad without a declaration for a drug covered by the Opium Act is punishable. The Central Administrative Office (CAK) legalises these statements. The website www.hetcak.nl contains all information about travel with medicines covered by the Opium Act.

4. How do I use medicinal cannabis oil?

Usually you start with a low dose. Depending on the effect, you can gradually adjust the dose. (see section 9 for dosing with drops or a syringe).

- *Bediol CBD 2.0%/THC 1.3% oil, 10 ml;* *0.05 ml = 1 mg CBD and 0.65 mg THC = 2 drops*
- *Bedica THC 2.0% oil, 10 ml;* *0.05 ml = 1 mg THC = 2 drops*
- *Bedrocan THC 2,0% oil, 10 ml;* *0.05 ml = 1 mg THC = 2 drops*
- *Bedrolite CBD 2.0% oil, 10 ml;* *0.05 ml = 1 mg CBD = 2 drops*
- *Bedrolite CBD 10.0% oil, 10 ml;* *0.05 ml = 5 mg CBD = 2 drops*

The oil is only suitable for oral use. Start according to the set up scheme below. Depending on the observed effect, increase the number of drops. The use can be different per individual. The cannabis plant is a natural product which is subject to variations in the cultivation. The content of CBD per bottle however does not vary.



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Example set up regimen (NOTE! You can stop setting up the dosage at a point where you experience the most relief of your symptoms. Maximum of 3x per day 0.25 ml):

Day 1-2: Day 3-4: Day 5-6: Day 7-8: Day 9 and further:	<u>With a dosing syringe</u> 2-3 times a day 0.05 ml 2-3 times a day 0.1 ml 2-3 times a day 0.15 ml 2-3 times a day 0.20 ml Etc. Maximum amount per day: 3 times 10 drops Or 3 times a day, 0.25 ml
Day 1-2: Day 3-4: Day 5-6: Day 7-8: Day 9 and further:	<u>With drip pipette</u> 2-3 times a day 1-2 drop(s) 2-3 times a day 2-3 drops 2-3 times a day 3-4 drops 2-3 times a day 4-5 drops etc. Maximum amount per day: 3 times 10 drops Or 3 times a day, 0.25 ml

See section 9 for instructions on dosing with drops or a syringe.

Bedrolite CBD 10% oil, 10 ml for epilepsy; 10% = 100 mg / ml

The initial dose for children is 0.5 mg/kg/day divided into 2 doses. Adults start with 0.2 mg/kg/day divided into 2 doses. Upon review, the dose may be increased. Adults may receive up to a maximum of 25 mg/kg/day, divided into 2 doses. In the schemes below, you will find an example for children (example 1) and for adults (example 2). The oil is applied under the tongue. The cannabis plant is a natural product which is subject to variations in the cultivation. The content of CBD per bottle however does not vary.

Example 1, set up scheme for children:

Week 1:	0.5 mg/kg/day divided into 2 doses
Week 2:	1 mg/kg/day divided into 2 doses
Week 3:	2 mg/kg/day divided into 2 doses
Week 4:	3 mg/kg/day divided into 2 doses
Week 5:	4 mg/kg/day divided into 2 doses
From week 6 on:	5 mg/kg/day divided into 2 doses
The neurologist determines whether the dosage should be further increased.	

Example 2, set up scheme for adults:

Day 1-3:	2x per day 0.05 ml
Day 4-6:	2x daily 0.1 ml
Day 7-10:	2x per day 0.15 ml
Day 11-13:	2x per day 0.2 ml
Day 14-17:	2 x 0.25 ml daily
Day 18 and further:	if necessary, increase further with 0.05 ml

See section 9 for dosing with drops or a syringe.

How long does it work?

The effect sets in quickly (within 30 minutes), the maximum effect is reached after 2-3 hours and the total effect lasts up to 4-8 hours. However, this may differ per individual. After 6-7 days all substances are removed from the body.

How long should I continue to use this medicine?

Use the medicinal cannabis as long as you suffer from symptoms. If you don't notice any improvement of the symptoms after 1 to 2 weeks of usage, please consult your doctor or pharmacist. The dose may need to be increased or you might need to use a different variety of cannabis oil. It is also possible that you may not benefit from the use of cannabis.

Have you used too much of the cannabis oil?

It takes 4-8 hours before the effects wear off.

What should I do if I forgot to take a dose?

Do not worry if you miss a dose. However, if you have been using the medicine for a few weeks in a high dose, you may suffer from withdrawal symptoms.

- If you are taking this medicine once a day: take the forgotten dose anyway. Wait 8 hours before taking the next dose.
- If you are taking this medicine 2 times a day, take the forgotten dose anyway. Wait 4 hours before taking the next dose.

5. What are the possible side effects?

Aside from the desired effect, cannabis can also cause side effects. Usually these side effects disappear automatically after a few hours. Patients generally tolerate medicinal cannabis well. Side effects usually occur when using higher doses or in combination with a drug that enhances the side effects (e.g. alcohol). Usually low doses are sufficient,



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therefore adverse reactions occur in a relatively low rate. The main side effects are the following.

Bedica THC 2.0% oil; Bedrocan THC 2.0% oil; Bediol CBD 2.0% / THC 1.3% oil

Regularly: 'High' feeling, this is a happy, stimulated mood that slowly morphs into a satisfied sensation of serenity and peace. Also lethargy, hunger, a more intense experience of colours and music, and a loss of sense of time and place can occur.

Sometimes: Feelings of dismal, especially in the elderly, and a sense of fear, anxiety and confusion. This can especially occur when the dose is too high or if you use cannabis for the first time. Therefore, make sure you are in a quiet place and there is someone with you when using cannabis for the first time. Cannabis can exacerbate existing psychiatric symptoms and disorders, such as schizophrenia (psychosis). You may then experience hallucinations (imagination). Make sure your doctor is aware of these symptoms before using the oil. **Restlessness** and insomnia. Consult your doctor or pharmacist if you suffer from these side effects.

Rarely: Dizziness, headache, hot or cold hands and feet, red burning eyes and a dry mouth. These side effects usually disappear after a few hours. **Heart palpitations**, rapid heartbeat, **increase in blood pressure**, chest pain. In rare cases this may lead to a heart attack. If you suffer from **angina pectoris (cardiac cramps)**, your symptoms may worsen. Please warn a doctor if this occurs. The cardiac side effects will diminish within 1 hour. People with congenital cardiac arrhythmias, **prolonged QT interval** or the **Brugada syndrome** may experience worsening of their symptoms. If you have any of these conditions, you may NOT use this medicine.

Very rarely: For prolonged and frequent use of high doses: **risk of addiction** or **mental dependence**. Stopping your medicinal cannabis may cause withdrawal symptoms to occur, such as nausea, restlessness, irritability, insomnia.

Bedrolite CBD 10% oil; Bedrolite CBD 2.0% oil

The side effects of CBD are not fully known yet. You will not get 'high' due to CBD. Consult your doctor or pharmacist if you suffer too much from any of the above-mentioned side effects, or if you experience other side effects that you are concerned about.

Dependence

Dependence generally does not occur if you use cannabis only as a medicine. You usually use medicinal cannabis in a lower dose than in the case of recreational use of cannabis. However, you do need to be careful if you have previously experienced addiction. Prolonged use of high doses of cannabis can lead to dependence. Stopping can cause withdrawal symptoms, such as restlessness, irritability, insomnia and nausea. As far as is known, it is mainly THC that causes the addictive effects. Therefore the risk of dependence is low and not expected with these oils.

6. Can I use cannabis oil with my other medicines?

Do you use any other medication?

The drugs with which the most important interactions occur are other drugs that affect your responsiveness. With these medications, the package is often labelled with a **yellow warning sticker**. The effects on performance of skilled tasks (e.g. driving) reinforce each other. Do not drive a car if you are taking 2 or more of these medicines. The cannabinoids in the cannabis oil are converted in the liver. Certain medicines may therefore interact with cannabis. Also, drinking grapefruit juice can reduce the conversion of cannabinoids in the liver. Grapefruit juice should therefore be avoided. You may use cannabis in combination with blood thinners like acenocoumarol and fenprocoumon if you are under the control of the thrombosis service (in Dutch: trombosedienst; this is a special health service in the Netherlands for patients using certain types of coumarins). Cannabis oil may interact with phenytoin and carbamazepine. The combination may only be applied if you are monitored by a neurologist. The pharmacist will check whether cannabis oil can be used with the rest of your medication.

7. How do you store medicinal cannabis oil?

Keep medicinal cannabis oil out of the sight and reach of children. The cannabis oil can be stored at both refrigerator and room temperature (minimum 2 °C and up to 25 °C). Do not use the cannabis oil after the expiration date. The shelf life can be found on the label of the packaging. Ask your pharmacist what to do with the medicinal cannabis you no longer use.

8. Contents of the pack and other information.

What cannabis oil contains:

- The active ingredients of medicinal cannabis are THC and/or CBD. See the label for the active substances present in the oil. Bedrolite does not contain THC.
- The other ingredients in this medicine consist of refined arachis oil (peanut oil).



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What does this medicine look like and how much does a package contain?

Cannabis oil is a brown to black oil.

The oil is packed per 10 ml in a brown glass vial with a dropper cap and a syringe.

Bedica and Bedrocan THC 2.0% oil contains 20 mg THC per ml

Bediol CBD 2.0% / THC 1.3% oil contains 20 mg CBD per ml and 13 mg THC per ml

Bedrolite CBD 2.0% oil contains 20 mg CBD per ml

Bedrolite CBD 10% oil contains 100 mg CBD per ml

9.0 Dosing cannabis oil.

The cannabis oil is supplied with a 1 ml syringe or a dropper cap. You can dose in ml with the syringe and drop with the dropper cap. Your label indicates what the usage instructions are.

9.1 Dropping with the (blue) dropper cap:

Twist the bottle cap, remove the transparent attachment, and twist the blue dropper on the vial. Turn the white cap of the blue rubber spout. Apply the number of drops on a spoon by gently squeezing the rubber and apply under the tongue.

9.2 Extraction of cannabis oil in the supplied syringe

Step 1 Turn the screw cap of the bottle

Step 2 Apply the supplied syringe onto the vial.

Step 3 Hold the bottle upside down.

Step 4 Withdraw the amount of ml as indicated on the label.

Step 5 Empty the contents of the syringe under the tongue.

This leaflet was last revised/approved in August 2017.