

BEDICA THC 2% oil, 10 ml
BEDICA THC 5% oil, 10 ml
BEDICA THC 10% oil, 10 ml
BEDROCAN THC 2% oil, 10 ml
BEDROCAN THC 5%, 10 ml
BEDROCAN THC 10% oil, 10 ml
BEDIOL CBD 2% / THC 1,3% oil, 10 ml
BEDIOL CBD 4% / THC 2,8% oil, 10 ml
BEDROLITE CBD 2% oil, 10 ml
BEDROLITE CBD 10% oil, 10 ml
BEDROCAN / BEDROLITE THC 10% / CBD 5% oil, 10 ml
For sublingual use

MEDICINAL CANNABIS OIL

This leaflet contains important information about medicinal cannabis oil. Before use, read the whole leaflet and keep it safely. Do not share this medicine with others as it could be harmful to their health.

If you are experiencing side effects or have any further questions please contact Transvaal Apotheek.

CONTENTS

- 1 What is medicinal cannabis oil?
- 2 What is it used for?
- 3 Frequently asked questions about using cannabis oil
 - 3.1 When am I not allowed to use it?
 - 3.2 When do I need to be extra careful with cannabis oil?
 - 3.3 Other frequently asked questions
- 4 Dosage and use
 - 4.1 Dropper cap or syringe
 - 4.2 What should I do if I forget a dose?
 - 4.3 What should I do if I have used too much cannabis oil?
- 5 Potential side effects
 - 5.1 The main side effects of Bedica oil, Bedrocan oil and Bediol oil
 - 5.2 The main side effects of Bedrolite oil
 - 5.3 Dependency
- 6 Can I use cannabis oil with other medicines?
- 7 How should I store medicinal cannabis oil?
- 8 Package contents and further information
- 9 Can I stop using cannabis oil at any time?

1 WHAT IS MEDICINAL CANNABIS OIL?

Medicinal cannabis oil is made from the dried flowers of the female cannabis plant. The cannabis plant is a **natural product**. Other names for cannabis are marijuana or weed.

The **active ingredients** of medicinal cannabis include dronabinol (THC) and cannabidiol (CBD).

There are **various oils** containing differing strengths of THC or CBD. The oil that is the most suitable for you depends on your symptoms. Your pharmacist will discuss this with your doctor. Medicinal cannabis that is provided by a pharmacy complies with the highest quality standards and is intended only for use as a medicine. You will need a prescription from your doctor for medicinal cannabis.

2 WHAT IS IT USED FOR?

Medicinal cannabis is used to supplement other treatments, to relieve side effects or if medicines are not helping enough. It doesn't cure you, but it can help to relieve your symptoms. Often, dosages of other medicines can be reduced due to medicinal cannabis. Cannabis is used when other medicines are not effective enough, e.g. for:

- pain, muscle cramps and muscle spasms associated with multiple sclerosis or damage to the spinal cord
- nausea, poor appetite, weight loss, weakness associated with cancer, HIV infection and hepatitis C
- chronic pain (mainly if it originates from the nervous system)
- Gilles de la Tourette syndrome
- therapy resistant glaucoma
- epilepsy

Cannabis also seems to have a favorable effect on other conditions. Research on this is being done.

For more information see www.cannabis-med.org

3 FREQUENTLY ASKED QUESTIONS ABOUT USING CANNABIS OIL

3.1 When am I not allowed to use it?

Do not use medicinal cannabis if you:

- have a tendency to psychotic disorders
- have Brugada syndrome
- are pregnant or want to become pregnant
- are breastfeeding
- have glaucoma in which case you may not use CBD

3.2 When do I need to be extra careful with cannabis oil?

Be **extra careful** with:

- other psychological/psychiatric problems
- disorders of heart rhythm
- angina pectoris
- ischemic heart disease
- congenital long QT interval syndrome (disorder of heart rhythm)

Also **take care** if you know you have a tendency to quickly become dependent on certain substances.

3.3 Other frequently asked questions

Can I eat and drink anything I want?

Do not eat grapefruit or drink **grapefruit juice**. This enhances the effect of cannabis oil and can cause side effects.

Can I drink alcohol?

Be careful with alcohol if you are using cannabis oil. You may drink alcohol if you are using Bedrolite CBD.

Can I drive a car?

Cannabis users with daily use: do not drive any motorized vehicle **the first two weeks**. Incidental use of cannabis: do not drive for **15 hours after intake**.

If you are using Bedrolite CBD cannabis oil then you **are allowed** to drive.

For more information see: www.rijveiligmetmedicijnen.nl.

Can I travel?

Medicinal cannabis oil falls under the Netherlands Opium Act. The possession and use of medicinal cannabis oil is forbidden in many countries. If you want to take it with you then you will need an official medical statement. You can get this from the CAK on request. For more information see: www.hetcak.nl

How long does medicinal cannabis oil work for?

It takes effect very quickly within 30 minutes. It reaches a peak after 2-3 hours and stays effective for 4-8 hours. Its exact effects may vary from person to person. It can take up to 3 weeks before all the substances disappear from the body.

How long should I continue to use this medicine?

Use the medicinal cannabis oil for as long as you have symptoms. Talk to your doctor or pharmacist if your symptoms have not improved after 1 to 2 weeks. Maybe the dosage needs to be increased or you need to use another sort of cannabis oil. It is also possible that medicinal cannabis oil will not be of any benefit to you.

4 DOSAGE AND USE

Your dosage will be printed on the label. You will usually begin with a low dosage. Depending on its effect you can gradually build up the dosage. Your doctor or pharmacy will help you with this.

Bedica THC 2%, Bedrocan THC 2%, Bediol CBD 2%/THC 1,3%, Bediol CBD 4%/THC 2,8% and Bedrolite CBD 2% dosage can be increased to a maximum of 3 times a day 30 drops. This equals 3 times a day 0,75ml. **Bedrocan THC 5% and Bedica THC 5%** can be increased to a maximum of 3 times a day 20 drops. This equals 3 times a day 0,5 ml. **Bedrocan THC 10%, Bedica THC 10% and Bedrocan/Bedrolite THC10%/CBD5%** dosage can be increased to a maximum of 3 times a day 10 drops, which equals 3 times a day 0,25ml. **Bedrolite CBD 10%:** start with a low dose (e.g. 0,05mg/kg/day) divided in 2 doses. Increase weekly up until a maximum of 25mg/kg/day, divided in 2 doses.

4.1 Dropper cap or syringe

Medicinal cannabis oil is delivered with a 1 ml syringe and a dropper cap (on request only).

Drawing up the cannabis oil into the accompanying syringe:

- 1 Screw the top off the bottle
- 2 Slide the syringe into the bottle
- 3 Turn the bottle upside down
- 4 Draw up the number of milliliters shown on the label
- 5 Empty the contents of the syringe under your tongue

RIGHT: 0.05 ml ✓ **✗ WRONG: 0.5 ml**



Taking the drops using the blue dropper cap:

- 1 Screw the top off the bottle
- 2 Remove the transparent holder
- 3 Screw the blue dropper cap onto the bottle
- 4 Unscrew the white top from the blue rubber spout
- 5 Put the prescribed number of drops on to a spoon by gently squeezing the rubber spout
- 6 Put the spoon containing the drops under your tongue

Under the tongue

The oil is only suitable to be taken by mouth (under the tongue). Hold the oil under your tongue for 1 minute then swallow it. Follow the dosage chart.

Tip

The oil may have a bitter taste. It helps to eat a few olives or a piece of banana.

4.2 What should I do if I forget a dose?

It doesn't matter if you miss a dose. We advise the following:

- If you use it once a day take the forgotten dose anyway. Take the next dose after 8 hours.
- If you use it twice a day take the forgotten dose anyway. Take the next dose after 4 hours.
- If you use this medicine 3 times a day, miss a dose if you are more than 2 hours late taking it.

4.3 What should I do if I take too much cannabis oil?

Just wait quietly and possibly miss your next dose. It takes 4-8 hours for the effect to wear off.

DOSAGE

EXAMPLE

Please note!! You can stop increasing your dosage when you feel the most relief of your symptoms.



	Using the syringe
Days 1-2	0.05 ml 2-3 times a day
Days 3-4	0.1 ml 2-3 times a day
Days 5-6	0.15 ml 2-3 times a day
Days 7-8	0.20 ml 2-3 times a day
Day 9 onwards	etc.



	Using the dropper cap
Days 1-2	1-2 drops 2-3 times a day
Days 3-4	2-3 drops 2-3 times a day
Days 5-6	3-4 drops 2-3 times a day
Days 7-8	4-5 drops 2-3 times a day
Day 9 onwards	etc.

BEDROLITE CBD 10% OIL

EXAMPLE

BUILDING UP THE DOSAGE IN CHILDREN

Week 1	0.5 mg/kg/day spread over 2 doses
Week 2	1 mg/kg/day spread over 2 doses
Week 3	2 mg/kg/day spread over 2 doses
Week 4	3 mg/kg/day spread over 2 doses
Week 5	4 mg/kg/day spread over 2 doses
Week 6 onwards	5 mg/kg/day spread over 2 doses

The neurologist will decide if the dosage needs to be further increased.



BUILDING UP THE DOSAGE IN ADULTS

Days 1-3	0.05 ml twice a day
Days 4-6	0.1 ml twice a day
Days 7-10	0.15 ml twice a day
Days 11-13	0.2 ml twice a day
Days 14-17	0.25 ml twice a day
Day 18 onwards	etc.



Depending on the effect the dosage may be increased. Adults may increase it to a maximum of 25 mg/kg/day.

5 POSSIBLE SIDE EFFECTS

Medicinal cannabis can have side effects but they are not very common. Side effects usually disappear on their own after a few hours. They can occur if the dosage is very high, or if another substance is being used that strengthens the side effects (alcohol for example). Consult your doctor or pharmacist if you are having problems with one of the side effects listed below, or if you have a side effect that is not listed below.

5.1 The main side effects of Bedica oil (2%, 5% and 10% THC), Bedrocan oil (2%, 5% and 10% THC), and Bediol oil (2% CBD/1.3% THC and 4% CBD/THC 2.8%)

Common (more than 3 in 1000):

- Feeling of being 'high': cheerful, alert mood that slowly changes to feelings of satisfaction, calm and peace.
- Lethargy, hunger, experiencing colors and music more intensely and loss of a sense of time and place.

Uncommon (1 to 3 in 1000):

- Somber mood and feelings of panic, anxiety and confusion. Especially if the dosage is too high or if you are using the medicine for the first time. When using the medicine, sit in a quiet place and make sure you have someone with you.
- Worsening of existing psychological problems. Tell your doctor about these problems before using the oil.
- Restlessness and sleeplessness.

Rare (0.1 to 1 in 1000):

- Dizziness, headache, warm or cold hands and feet, red burning eyes, dry mouth. These side effects normally disappear after a few hours.
- Palpitations, rapid pulse, raised blood pressure, chest pain. In rare cases this can cause a heart attack. If you have angina pectoris, the symptoms may be worsened. The side effects affecting the heart start to disappear after 1 hour, but it is advisable to contact a doctor.

Very rare (<0.01%): Dependency

- THC in particular may cause dependency, but if you use the oil as prescribed then the risk that you will become dependent on it is very small.

5.2 The main side effects of Bedrolite oil (2% CBD or 10% CBD)

Bedrolite oil contains CBD. The most commonly reported side effects in clinical trials are: sleepiness, fatigue, reduced appetite, diarrhoea, liver function test abnormalities and skin rashes. CBD does not make you high.

5.3 Dependency associated with the use of medicinal cannabis

If you take high dosages of the oil for a few weeks you may develop withdrawal symptoms such as mild forms of restlessness, irritability, sleeplessness and nausea.

6 CAN I USE CANNABIS OIL WITH OTHER MEDICINES?

There is a risk of interactions if you are using the following medicines:

- **Medicines that reduce your reaction time.** This medication and cannabis oil enhance each other's effects. These medicines often have a **yellow warning sticker** on the packaging. Do not drive if you are using 2 or more of such medicines.
- **Blood thinners** (such as acenocoumarol or phenprocoumon): you may only use cannabis oil if you are having regular check-ups with the thrombosis service. Tell the thrombosis service if you are going to use cannabis oil.
- **Phenytoin, clobazam and carbamazepine:** only take this combination if you are having regular check-ups with a neurologist.

The pharmacist will check if you can use medicinal cannabis oil together with your other medication.

7 HOW SHOULD I STORE MEDICINAL CANNABIS OIL?

Make sure that children cannot reach the medicinal cannabis oil. Store the oil between 15° C and 25° C, so at room temperature. Do not store in a refrigerator. Do not use the oil after its expiry date. This is printed on the package. Ask your pharmacist what you should do with any oil that you are no longer using.

8 PACKAGE CONTENTS AND FURTHER INFORMATION

What are the ingredients of the medicine?

- The active ingredients of medicinal cannabis are THC and/or CBD. The active ingredients of the oil are printed on the label. Bedrolite does not contain THC.
- Medicinal cannabis oil contains refined arachis oil (peanut oil). This refined arachis oil is cleansed of peanut proteins and can be used by people with a peanut allergy.

What does this medicine look like, and how much is in a package?

Cannabis oil is green-brown to black in color. The oil is packed per 10 ml in a brown glass bottle with a dropper cap.

9 CAN I STOP USING CANNABIS OIL AT ANY TIME?

It is safe to stop using cannabis oil. You don't need to taper off the dosage.

10 DATE OF LAST REVISION OF THE TEXT

This leaflet was last revised May 11th 2022.

MEDICINAL CANNABIS OIL IN BRIEF

WHAT IS IT?

Medicinal cannabis has a number of ingredients including dronabinol (THC) and cannabidiol (CBD).

It is made in a number of mixtures and strengths, therefore its effects can be different. There are six different oils of varying strengths:

Bedica THC (2%, 5% and 10%)

Bedrocan THC (2%, 5% and 10%)

Bediol (THC 1,3% / CBD 2% and THC 2,8%/CBD 4%)

Bedrolite CBD (2% and 10%)

Bedrocan THC10%/Bedrolite CBD 5%

Your pharmacist and doctor will together decide which oil is the most suitable for you.

WHAT IS IT USED FOR?

Medicinal cannabis is used to supplement other treatments, to relieve side effects or if medicines are not helping enough. It doesn't cure you, but it can help to relieve your symptoms. Often, dosages of other medicines can be reduced due to medicinal cannabis.

HOW DO I TAKE IT?



Using the syringe, draw up the prescribed number of milliliters from the bottle and empty the syringe under your tongue. Hold the oil there for 1 minute and then swallow it.

or



Using the dropper cap, put the prescribed number of drops on to a spoon and empty the spoon under your tongue

HOW SHOULD I STORE IT?



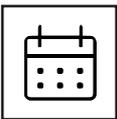
Storage temperature: between 15 and 25° C.
Keep out of reach of children.

HOW LONG DOES IT WORK FOR?



The oil starts to work within 30 minutes and its effect lasts for 4 to 8 hours. After 3 weeks all the substances will have disappeared from the body.

HOW LONG CAN I USE IT FOR?



For as long as you have symptoms. Talk to your doctor or pharmacist if your symptoms have not improved after 2 – 3 weeks.

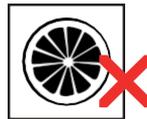
WARNINGS!



Do not use it if you are pregnant



Do not breastfeed



Do not take it with grapefruit or grapefruit juice



Be careful with alcohol



Do not drive a car the first 2 weeks if using THC. You may drive if you are using CBD

CAN I TRAVEL?



If you are travelling abroad you will need an official certificate. This can be requested from <https://www.hetcak.nl>

SIDE EFFECTS AND INTERACTIONS

Main side effects: Feeling 'high', lethargy, hunger, experiencing colors and music more intensely, loss of sense of time and place.

Main interactions with:

- medicines that reduce your reaction time
- blood thinners (such as acenocoumarol or phenprocoumon)
- phenytoin and carbamazepine

FORGOTTEN A DOSE?

No problem, still take it but wait a few hours until the next dose.

TAKEN TOO MUCH?

Wait quietly, and perhaps miss the next dose. The effect will wear off in 4-8 hours.



Produced by Transvaal Apotheek
Kempstraat 113, 2572GCThe Hague

E: cannabis@transvaalapotheek.nl
T: 070-2055637 (Mon-Fri 10.00 – 16.00)