

Patient leaflet

For use only by Cannabis license/prescription holders

Cannabis oil products

סם מסוכן
Controlled Substance



| Each ml contains | | CBD | THC | קטגוריה | Group | |
|------------------|----------|------------|------------|---------------------|------------------|---------------------|
| CBD mg | THC mg | | | | | |
| 300 | up to 5 | 30% | Up to 0,5% | Cannbis oil T0/C30 | CBD Rich | CANNABIS OIL |
| 280 | up to 15 | 28% | Up to 1,5% | Cannbis oil T1/C28 | | |
| 240 | up to 15 | 24% | Up to 1,5% | Cannbis oil T1/C24 | | |
| 200 | up to 15 | 20% | Up to 1,5% | Cannbis oil T1/C20 | | |
| 180 | up to 30 | 18% | Up to 3% | Cannbis oil T3/C18 | | |
| 150 | up to 30 | 15% | Up to 3% | Cannbis oil T3/C15 | | |
| 120 | up to 30 | 12% | Up to 3% | Cannbis oil T3/C12 | | |
| 100 | up to 50 | 10% | Up to 5% | Cannbis oil T5/C10 | | |
| 120 | 120 | 12% | 12% | Cannbis oil T12/C12 | | |
| 100 | 100 | 10% | 10% | Cannbis oil T10/C10 | | |
| 80 | 80 | 8% | 8% | Cannbis oil T8/C8 | THC/CBD BALANCED | |
| 50 | 50 | 5% | 5% | Cannbis oil T5/C5 | | |
| 30 | 30 | 3% | 3% | Cannbis oil T3/C3 | | |
| up to 15 | up to 15 | Up to 1,5% | Up to 1,5% | Cannbis oil T1/C1 | | |
| up to 20 | 100 | Up to 2% | 10% | Cannbis oil T10/C2 | THC Rich | |
| up to 20 | 120 | Up to 2% | 12% | Cannbis oil T12/C2 | | |
| up to 30 | 150 | Up to 3% | 15% | Cannbis oil T15/C3 | | |
| up to 30 | 180 | Up to 3% | 18% | Cannbis oil T18/C3 | | |
| up to 40 | 220 | Up to 4% | 22% | Cannbis oil T22/C4 | | |

* Each 1 ml contains about 30 drops

CBN concentration for all categories is up to 1%

Other ingredients: cannabis terpenes up to 2.5%

Active ingredients

There are over 500 chemical compounds in the cannabis plant. The most well-known and researched active ingredients in the cannabis plant are CBD and THC cannabinoids. Cannabis products are classified according to the concentration of these substances.

Other known components are called Terpenoids, with separate action mechanisms that create synergy (known also as the Entourage Effect) with cannabinoids.

This combination is expressed in medical properties, such as: pain reduction, reduction in anxiety, anti-inflammatory activity, quality of sleep, and more.

Read the entire leaflet carefully before using this product. This leaflet contains concise information about this product. If you have any further questions, consult your doctor, pharmacist, or training center representative.

Prior to initial use or any other question it is recommended to contact Bazelet Pharma guidance service: 072-22-11-500

This product has been prescribed specifically for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

The Cannabis product is classified as a controlled substance; using it is prohibited unless it has been legally licensed/prescribed. Possession of cannabis and the place it is used for medicinal purposes are regulated by the Ministry of Health Cannabis Unit. (Reference 48046317: Revised conditions for license/prescription to possess and place of use of cannabis for medicinal purposes - Cannabis Unit, Ministry of Health). Using a Controlled substance in the presence of minors or in public is strictly prohibited.

Do not take a dangerous drug or any of its products out of Israel without special permission.

Read and follow the restrictions and conditions listed on your patient license/prescription for using and possessing the product.

This leaflet is not a substitute for a conversation with your doctor, pharmacist, or training center representative.

1. What is cannabis intended for?

These medical indications are subject to the appropriate stipulations listed in Ministry of Health (Israeli Cannabis Unit) Procedure 106.

2. Before using cannabis

✘ Do not use this product if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients that this product contains or if you develop sensitivity while using it.
- You are pregnant, planning to become pregnant, or if you are breastfeeding.
- You have an active psychosis or a (first-degree) family history of psychotic disease.

! **Special warnings related to use of this product:**

- Diabetics' patients** - Taking cannabis may cause your blood sugar level to drop. You are advised to have with you a snack or a sweet or a sweetened soft drink before you start using the product.
- Patients who have liver cancer (hepatoma)** - You are advised to avoid using cannabis products that contain THC.
- Substance abuse and dependence / cannabis addiction** - A medical team should be updated if you need a growing dose of cannabis to improve your medical condition.

Before you start treatment with cannabis, tell your doctor if:

- You have heart condition or a severe blood vessel disease such as: congestive heart failure, heart-related chest pain, a previous heart attack, uncontrolled high blood pressure, or a heart-rhythm or heart-beat problem, or if changes in heart-beat and blood pressure are observed after you start treatment.
- You have a liver or kidney disease.
- You have active psychoses or you have had a psychotic episode in the past.
- You have an anxiety disorder.
- You have a (first degree) family history of a significant psychiatric condition, particularly if you are younger than 30 years old.
- You have a history of addiction to a medicine or to any substance or a history of drug abuse.
- You are elderly, particularly if you are having difficulty performing daily tasks such as preparing food and hot drinks.
- You have schizophrenia or bipolar disorder.

Tests and follow-up

- Your license/prescription is granted on condition that you undertake medical follow-up at least every three months during the first year

Our training and consultation center is available to you, free of charge:

🌐 bazelet-pharma.co.il 📞 054-7342697 📞 072-22-11-500 Find us on



of treatment, by a doctor whose information is listed on the license/prescription. From the second year onward, follow-up is required at least every six months.

- If you are taking valproate (for epilepsy) together with cannabis, monitoring liver function is recommended.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell the doctor.

Your doctor will evaluate the potential extent of interactions and will decide whether the result is clinically significant before approving a combined treatment. Your doctor will order follow-up, dose adjustment, stopping treatment, or other precautions.

In particular tell your doctor if you are taking:

- **Medicines that suppress the central nervous system** such as medicines for sleep disorders, sedatives, anti-anxiety medicines and anti-psychotics, or opiate pain relievers. These medicines may increase the sedative and muscle relaxing effects and this can lead to an increased risk of falling and other accidents. Using this product together with opiates can increase the risk of respiratory depression (slow and ineffective breathing).
- **Muscle-relaxing medicines** such as baclofen, or benzodiazepines. May cause reduced muscle strength and power, which lead to an increased risk of falling.
- **Medicines for reducing blood-glucose level** - Blood-glucose levels may be reduced too far and your dose may need to be adjusted when you start or change your cannabis treatment.
- **Medicines for reducing blood pressure** - Blood pressure may be reduced too far and your dose may need to be adjusted.
- **Medicines with a sympathomimetic effect** (including medicines for local eye or nose treatment that can potentially be absorbed in the body) - There may be a greater risk of tachycardia (fast heart rate) or increased blood pressure.
- **Anticoagulants that contain warfarin (Coumadin)** - INR values may increase.
- **Local medicines for reducing pressure inside the eye (glaucoma).**
- **Medicines for increasing sexual function** - May increase the risk of heart-attack.
- **Antibiotics for skin infections** - fusidic acid.
- **HIV medicines.**
- **Epilepsy medicines** - valproate, topiramate, rufinamide, clobazam, zonisamide, eslicarbazepine.
- **Medicines with anticholinergic effects** (such as tricyclic antidepressants, antihistamines used to treat allergy) - There may be an increased chance of tachycardia, dizziness, and mania.
- **Azelastine** - For allergy in the eye.
- **Amphetamines or amphetamine derivatives** - medicines for slimming, attention disorders, and dental treatment (adrenalin which is sometimes used as an anesthetic) - may cause a rise in blood pressure and rapid heart rate.
- Drugs that have an effect on immune system suppression, **biological drugs or immunological drugs.**
- **Other medicines that may affect or may be affected by the breakdown of cannabis in the body:** barbiturates, carbamazepine, enzalutamide, phenobarbital, phenytoin, primidone, rifabutin, rifampin, hypericum, clarithromycin, cyclosporine, darunavir, erythromycin, itraconazole, ketoconazole, lopinavir, mifepristone, ombitasvir, paritaprevir, ritonavir, saquinavir, verapamil, voriconazole, amiodarone, clopidogrel, fluconazole, fluorouracil, metronidazole, sulfamethoxazole, chloramphenicol, efavirenz, esomeprazole, fluoxetine, fluvoxamine, isoniazid, modafinil, omeprazole, oxcarbazepine, theophylline, caffeine, clozapine, duloxetine, estradiol, estrogen, lidocaine, melatonin, mexiletine, mirtazapine, olanzapine, propranolol, rasagiline, ropinirole, triamterene, zolmitriptan.

The information about combining cannabis with medicines is not yet sufficiently based on proper medical studies. So, whenever you encounter a side effect that might be the result of a combination of some medicine with cannabis, you are advised to report this to your

doctor and be more careful.

If you are taking any medication, do not discontinue or change it without your doctor's advice.

Using this product and food

- Do not drink grapefruit juice while you are taking cannabis.
- Cannabis may cause your blood sugar level to drop and make you feel tired and dizzy. It is advised not to take it on empty stomach. You are advised to have with you a snack or sweet, or sweetened soft drink **before** you take the product.
- Eating a light meal is recommended 30 minutes **after** taking the product.

Using this medicine and alcohol consumption

Do not drink wine or any other alcoholic beverages during treatment with cannabis, particularly when you start treatment or when the product is changed or your dose is modified. Drinking alcoholic beverages during treatment with cannabis may increase certain effects such as loss of balance or reduced reaction-time. This can impair your ability to drive and operate machines and increase your risk of falling and other accidents.

Pregnancy, breastfeeding, and fertility

- Do not use cannabis if you are pregnant, are planning to become pregnant, or if you are breastfeeding.
 - Women and men must use effective contraceptives during the course of treatment with cannabis and for three months after stopping treatment.
 - If used during pregnancy, the baby may have a low birth weight.
 - Fertility - Using cannabis may cause a decrease in sperm count and sperm motility and has a negative effect on embryo implantation.
- If you are pregnant or breastfeeding, consult your doctor before taking any medicines.

Driving and using machines

- Studies have shown that the active ingredients in cannabis affect concentration, reaction time, ability to estimate time and spatial perception.
- Do not drive or use dangerous machines while consuming, or when an active ingredient is present, or breakdown ingredients in the patient's blood.
- **The instructions for driving and using machines are consistent with the Israel Transport Regulations (drugs that are not dangerous drugs) - 2018.**
- Caution children against riding a bicycle or playing near a road, and similar activities.

3. How to use this product?

Always use this product according to your doctor's instructions. Check with your doctor, pharmacist or training center representative if you are not sure about your dose or about how to take this product. Only your doctor will determine your dose and how you should take this product. It is preferable to balance your chronic medicines, as far as possible, before you start using cannabis.

The recommended dose is usually:

Daily doses are highly individual and need to be adjusted by monitoring the dose over 24 hours.

A gradual increase in dosage in order to reach the lowest dose to reach balance between significant medical benefit and minimal side effects.

Patience! The process of reaching optimal dosage may take several weeks or even more.

Starting to use cannabis:

1. It is best to start using cannabis when you are at home.
2. It is best to start using cannabis for the first time in a relaxed atmosphere and in the presence of another responsible adult.
3. Start with a very low dose and monitor the effect. Keeping a tracking table is recommended.

Do not exceed the recommended dose.

Do not mix in or add any other substance to the cannabis product. The cannabis product is ready for use as it is and any additions may reduce the clinical efficacy of the treatment.

Method of use:

Cannabis Medical Oil

- Use the oil after a light meal (fruit or small snack) to prevent reduced sugar levels.
- Drip the desired amount of drops into a teaspoon. Hold the bottle vertically (90 degrees) to the spoon for accurate dripping. Cannabis oil is a viscous liquid and may drip relatively slow.
- Insert the spoon into the mouth under the tongue and slowly remove it.
- After this wait 1-2 minutes before swallowing to allow the oil to be efficiently absorbed.
- Wait about 15 minutes before drinking or eating. The effect should be felt after about half an hour to an hour.
- It is possible that the medical benefit will be felt only after a few weeks and therefore a continuum of treatment is important.
- Common dose is about 3-4 times a day. It is possible that the number of drops in each dose will vary according to the medical condition or the type and concentration of the oil.

If you have accidentally taken a higher dosage you may experience severe poisoning effects including dizziness, sleepiness, confusion, hallucinations (seeing or hearing things that are not there), delusions (believing in things that are untrue), anxiety or paranoia (increased anxiety or fearfulness), changes in heart rate associated with low blood pressure (feeling dizzy when getting up).

If you have taken an overdose, or if a child has accidentally swallowed/ inhaled some medicine, go immediately to a doctor or hospital emergency room and bring the product package with you. After an overdose you must see a doctor for follow-up.

Do not induce vomiting unless explicitly instructed to do so by a doctor.

If you forget to take the product at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

If you need to stop taking the product:

Consult your doctor before you decide to stop taking cannabis after you have used it regularly.

Discontinuing this treatment suddenly may affect your sleep, appetite, or emotions. You may experience withdrawal symptoms, including: agitation, irritability, headache, anxiety, depression, low stimulation threshold, difficulty concentrating, insomnia, appetite disorders, craving for the drug. Therefore, to prevent withdrawal symptoms and distress following a decision to stop your cannabis treatment, your doctor will instruct you how to gradually reduce your use until you stop completely.

Do not use this product in the dark! Check the label and the dose each time you use this product. Wear glasses if you need them.

If you have any further questions about using this product, consult your doctor or pharmacist.

4. Side effects

Using cannabis may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

Additional side effects:

Common side effects

- Dizziness or a feeling of levitation ("high").
- Unstable heartbeat, heart palpitations.
- Decreased glucose and / or blood pressure.
- Increased appetite.
- Poor coordination, instability, and concentration impairment.
- Fatigue and drowsiness or weakness.
- Changes in perception of time and space, short-term memory loss.
- Changing mood, anxiety.
- Cough and sore throat.
- Dryness and redness in the eyes.
- Headaches.
- Abdominal pain, digestive (vomiting and diarrhea).

Chronic long use side effects

- Dependence, addiction or abuse.
- Decreased hormone levels: prolactin, LH, FSH, and GH.
- Electrolyte balance disorders. Caution is required in patients with renal failure.
- Psychotic disorders in patients with a personal history or family history of these symptoms.

These effects usually disappear after a short time when you become accustomed to the product. Regular use of large quantities may cause permanent damage to your cognitive abilities.

Side effects of unknown frequency that are described in the literature: Allergic reaction, Cannabinoid arthritis, Heart rhythm disorders, Congestive heart failure

Decrease in body temperature and in body movement, and, in rare cases, paralysis

Hypomania (loss of ability to make rational decisions and irresponsible behavior).

Side effects that are usually caused by overdose and that require special attention:

Fainting, significant changes in your blood pressure, blood sugar levels, or breathing rate. In some cases and in people with a tendency, a high dose of this product, may cause a temporary outburst of psychotic episodes, anxiety, and hallucinations

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

5. How to store this product?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the product after the expiry date (exp. date) stated on the package/label. The expiry date refers to the last day of that month.

Storage conditions

- Store products for smoking or vaporization in a well-sealed package, in a dark and dry place at a temperature lower than 25°C.
- Cannabis oil extract is best used within one month of first opening.
- Do not throw away any cannabis product via wastewater or household waste. Ask the dispensing pharmacist how to throw away this product when you are not using it any more.
- Do not store in the same package with other medicines/medicinal products.

6. Additional information

What the products looks like and contents of the pack:

Cannabis oil packed in an airtight glass bottle and contains an extract mixed with the oil with a total weight of 10 grams.

Holder of manufacturing, processing and packaging license:

Bazelet Nechushtan LTD. PO Box: 156, Or Akiva.

Website: bazelet-pharma.co.il | Mail: info@bazelet-n.com

This leaflet was reviewed and approved by the Ministry of Health in April 2024