

מסוכן CONTROLLED SUBSTANCE

Information Leaflet for Medical Cannabis Product
Only for holders of license for medical cannabis use

Medical cannabis inflorescences Inhalation (smoking/evaporation)

Active ingredients

Cannabis inflorescence contains active ingredients named cannabinoids, classified according to the concentration of cannabidiol (CBD) and tetrahydrocannabinol (THC), which have the most significant medicinal activity.

Additional currently known ingredients, terpenoids and flavonoids, are likely to be therapeutically significant as well, but the scientific knowledge about their pharmacological effect is more limited.

The products are adjusted for each patient according to the concentration of active ingredients and the nature of the composition (Sativa/Indica).

Product table - Medical cannabis inflorescences (IMC - Medical Grade)

Type	Product name	THC	CBD	CBN*
CBD rich	Medical cannabis inflorescences T1/C20 CBD	1% (0.0% - 2.5%)	20% (16% - 24%)	0% (Up to 1.5%)
	Medical cannabis inflorescences T3/C15 CBD	3% (0.0% - 5%)	15% (11% - 19%)	0% (Up to 1.5%)
Balanced	Medical cannabis inflorescences T10/C10	10% (6% - 14%)	10% (6% - 14%)	0% (Up to 1.5%)
THC rich	Medical cannabis inflorescences Sativa T10/C2 Source/type of Sativa strain	10% (6% - 14%)	2% (0% - 3.8%)	0% (Up to 1.5%)
	Medical cannabis inflorescences Indica T10/C2 Source/type of Indica strain	10% (6% - 14%)	2% (0% - 3.8%)	0% (Up to 1.5%)
THC rich	Medical cannabis inflorescences Sativa T15/C3 Source/type of Sativa strain	15% (11% - 19%)	3% (0% - 5%)	0% (Up to 1.5%)
	Medical cannabis inflorescences Indica T15/C3 Source/type of Indica strain	15% (11% - 19%)	3% (0% - 5.5%)	0% (Up to 1.5%)
THC rich	Medical cannabis inflorescences Sativa T20/C4 Source/type of Sativa strain	20% (16% - 24%)	4% (0% - 7%)	0% (Up to 1.5%)
	Medical cannabis inflorescences Indica T20/C4 Source/type of Indica strain	20% (16% - 24%)	4% (0% - 7%)	0% (Up to 1.5%)

* cannabidiol (CBN) is a breakdown product of THC and indicates aging of the product.

Read the entire leaflet carefully before you start using this product. If you have any further questions, consult the medical team. Always take the product in accordance with the conditions of the medical cannabis license granted to you and the doctor's instructions. Read and follow the license restrictions and conditions as stated in the license for use and possession.

This product has been prescribed 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. In addition, passing the product to others may lead to loss of the license and is considered as a criminal offense.

The cannabis product is defined as a controlled substance, which is prohibited for use, unless lawfully licensed. Possession and place of cannabis use for medical purposes are in accordance with the regulations of the medical cannabis unit at the Ministry of Health.

It is strictly prohibited to use the product in the presence of minors.

Do not take this product out of Israel without a special permit.

When cannabis inflorescences in the formulation of cigarettes for smoking are used, take all the necessary precautions related to the use of fire.

TIKUN OLAM
MEDICAL CANNABIS

Do not violate the recommendation for mode of administration defined for the product, for example: do not swallow inflorescences. Swallowing inflorescences may cause abnormal side effects.

1. What is medical cannabis intended for?

Medical cannabis is intended for various diseases as defined by the medical cannabis unit at the Ministry of Health. The position of medical cannabis in the treatment sequence is in most cases after exhaustion of the standard treatments.

2. Before using medical cannabis

Do not use this product if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the product, or if you have developed sensitivity while using the product.
- You suffer from an active psychosis, or you or someone in your family (a first degree relative) have a history of schizophrenia, psychosis or other psychotic illness.
- You have a history of addiction or substance abuse (including cannabis) or alcohol.
- You suffer from bipolar disorder (episodes of depression alternating with episodes of mania).
- You are below the age of 18.*
- You are unable to be under follow up of the medical team.
- You are pregnant, suspect that you are pregnant, planning to become pregnant, or if you are breastfeeding.

* Except for certain indications as detailed in Procedure 106, Medical Cannabis Unit.

Special warnings about using this product

- Medical cannabis in all its forms has a potential for abuse. Do not give the product to any other person. Take all precautions to prevent any person other than the patient from having access to the product.
- Prolonged use may cause dependence! Consult the doctor if you feel that you are developing dependence or addiction to the product.
- Tell the doctor if you need increasing doses of the product to relieve your symptoms (i.e., you have developed tolerance).
- If you are about to undergo any surgery (including dental surgery) or any procedure associated with anesthesia, or if you are about to undergo laboratory tests while using the product, inform the doctor that you are taking this product.
- If you are sensitive to any food or medicine, you must inform the doctor prior to taking the product.
- Medical cannabis is suitable for patients who can adhere to the medical team's instructions over time.
- Diabetes patients - Cannabis consumption may lead to a decrease in blood sugar values. It is recommended to have a snack, or a sweet, or a cool sweetened beverage available before you start using the product. It is recommended to monitor sugar levels at the beginning of use.
- For patients suffering from liver cancer (hepatoma) - It is recommended to refrain from using cannabis product containing THC.

Before treatment with cannabis, tell your doctor if:

- You suffer or have previously suffered from dysfunction of the: liver, kidneys, heart or blood vessels (such as a heart rate problem), immune system (such as transplant recipients or patients undergoing chemotherapy).
- You suffer or have previously suffered from depression or anxiety.
- You suffer from high blood pressure, low blood pressure or diabetes.
- You have a history of addiction to tobacco or any other medicine (such as an opioid or benzodiazepine).
- You experience difficulties in performing daily activities such as preparation of hot food and drinks.

Use in children

This product is not intended for children and adolescents below the age of 18 years (Except for certain indications as detailed in Procedure 106, Medical Cannabis Unit).

Use in elderly patients

Elderly and frail patients may be more sensitive to the side effects of the product, such as somnolence and dizziness; therefore, great caution is required to prevent falls and other possible accidents (e.g. during hot food preparation). Until adaptation to the product is achieved, it is advisable to refrain from sudden transition from lying/sitting position to standing position, to prevent dizziness. Use of the product requires extreme caution for elderly patients with functioning limitations living alone.

Smoking

It is not recommended to mix cannabis with regular tobacco due to the concern of impairing the treatment efficacy.

Tests and follow up

Granting a license will be subject to medical follow up, according to the provision of Regulation 106, by the attending doctor whose details will be included in the license.

If you are taking valproate (for treatment of epilepsy) together with cannabis, it is also recommended to monitor liver functions during the combined use with cannabis.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and/or dietary supplements, tell the doctor or pharmacist prior to using this product. The doctor will assess the potential for drug interactions and determine whether the assessment result is clinically significant, requiring consideration prior to approving the combined treatment.

If required, the doctor will order follow up, dosage adjustments, treatment discontinuation or other precautions. Inform the doctor or pharmacist particularly if you are taking the following medicines (The following list indicates the active ingredients contained in the medicines. If you are not sure whether you are using any of these medicines, please consult the doctor or pharmacist):

- Medicines affecting the central nervous system** such as: analgesics (such as opioid analgesics), tranquilizers, sedatives, or anti-anxiety medicines (such as benzodiazepines), antihistamines (against allergy), medicines for treatment of mental disorders such as schizophrenia (phenothiazines, neuroleptics). These medicines may increase the sedative and muscle relaxing effects, thus leading to increased risk of falls and other accidents. Use in combination with medicines of the opiate class may also lead to increased risk of respiratory depression.
- Muscle relaxants** such as baclofen or benzodiazepines. A decrease in muscle strength and power may be caused, leading to increased risk of falls.
- Medicines for the treatment of hypertension or diabetes.**
- Medicines with sympathomimetic effect** (including medicines for topical ocular or nasal treatment with a potential of systemic absorption) - the risk of rapid heart rate (tachycardia) development or blood pressure elevation may increase.
- The herb Hypericum perforatum** (Also known as St. John's Wort).
- Anticoagulants containing warfarin (Coumadin) - INR should be monitored.**
- Topical agents for intraocular pressure (glaucoma) reduction.**
- Medicines for sexual potency elevation.**
- Antibiotics for treatment of skin infections** - fusidic acid.
- Anti-epileptic medicines** - valproic acid, topiramate, rifunamide, clobazam, oxcarbazepine, phenytoin, phenobarbital, primidone, zonisamide, carbamazepine.
- Medicines with anticholinergic activity** (such as tricyclic antidepressants, antihistamines used against allergy).
- Antifungal medicines** (such as ketoconazole, voriconazole, itraconazole, fluconazole).
- Macrolide antibiotics** (such as erythromycin, clarithromycin), **metronidazole or sulfamethoxazole.**
- Medicines for the treatment of tuberculosis** (such as rifampicin, rifabutin, isoniazid).
- Medicines against HIV or hepatitis C** belonging to the class of protease inhibitors or non-nucleoside reverse transcriptase inhibitors.
- Azelastine** or for the treatment of eye allergy.
- Amphetamine or their derivatives** - products for weight loss, attention and concentration deficit disorder and even for dental treatments (adrenaline sometimes used for anesthesia) - may lead to increased blood pressure and rapid heart rate.
- Additional list of medicines** which may affect or be affected by the process of cannabis breakdown in the body: Barbiturates, enzalutamide, primidone, cyclosporine, darunavir, lopinavir, mifepristone, ombitasvir, paritaprevir, ritonavir, saquinavir, verapamil, amiodarone, clopidogrel, fluorouracil, chloramphenicol, efavirenz, esomeprazole, omeprazole, fluoxetine, fluvoxamine, modafinil, theophylline, caffeine, clozapine, duloxetine, estradiol, estrogen, lisdexamine, melatonin, mexiletine, mirtazapine, olanzapine, propranolol, rasagiline, ropinorole, triamterene, zolmitriptan.

Follow up by the medical team is required throughout the period of treatment with the product. The follow up will be more frequent in the beginning of treatment and after every dosage change.

It is advisable to establish a stable treatment regimen with the chronic medicines, as much as possible, prior to initiation of medical cannabis use.

The current Traffic Ordinance (Section 64 B) and Traffic Regulations (substances not considered as controlled substances 2018) specify cases in which driving during the use of medical cannabis is allowed or prohibited, and these regulations must always be followed.

3. How to use this product?

Always use this product according to the medical team's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or the manner of treatment with the product. Only your doctor will determine your dosage and the manner of treatment.

Prior to starting using medical cannabis, the treatment goals should be determined, such as significant pain relief or improvement of function and/or quality of life. Evaluation of achieving or failure to achieve these goals will assist the medical team in assessment of the treatment benefit and in the decision regarding treatment continuation or discontinuation.

Adjustment of the daily and monthly dosage is individual for each patient and will be conducted by titration (gradual dosage elevation), which will assist in adjustment of the recommended daily amount in order to reach the minimal dosage providing a significant benefit with minimal side effects.

The plan of treatment with cannabis products will be designed in accordance with the titration protocol steps for change in the quantity (potency dependent) of cannabis products provided in the information booklet and the medical guide of the medical cannabis unit (IMC-GCP). The titration process will be accompanied by follow up by the medical team, who will guide you regarding the dosage and manner of product use, in accordance with your condition, response to treatment and side effects. At the end of the process, your optimal daily dosage will be determined.

The process of reaching the optimal dosage (titration) may take several weeks and sometimes even longer, and therefore your patience is required.

If any change subsequently occurs in your health or response to treatment, re-titration may be required.

Note: If the appropriate dosage is not reached after the titration process, you may discuss the possibility of switching to another THC/CBD concentration, another product or another mode of administration with the medical team. If required, combined treatment with 2 products containing different THC/CBD concentrations may be administered (for example: one product for the day and second product for the night).

Follow up by the medical team is required throughout the period of treatment with the product. The follow up will be more frequent in the beginning of treatment and after every dosage change.

It is advisable to establish a stable treatment regimen with the chronic medicines, as much as possible, prior to initiation of medical cannabis use.

Manner of use

Manner of product consumption: inhalation by smoking or by evaporation (using an inhalation device). You must receive instruction regarding the manner of consumption from a medical team member.

Consider the advantages of administration by inhalation (rapid effect) compared to the disadvantages, including potential damages of smoking, passive smoking in the patient's environment and combustion products.

Take the recommended dose by inhalation after a light sweetened meal (a fruit or juice) to prevent a drop in the sugar level (diabetes patients; consult the attending doctor regarding the need to eat something sweet and the need to adjust the dosage of anti-diabetic medications).

The effect will be experienced within several minutes.

To relieve the sensation of burning which may occur, it is recommended to drink cool water or a cool and sweetened soft beverage during and after the treatment.

The medical benefit may be experienced only after several weeks, therefore treatment continuum must be maintained.

Start at a minimal dosage and follow the effect. It is advisable to maintain a follow up table. During the first treatment week, you may take 1-2 inhalations per day. After about 1 week, you may gradually increase the number of inhalations until the desired effect is achieved.

A smoking product is usually taken about 3-4 times per day. The number of inhalations per intake may vary depending on the immediate medical condition or depending on the concentration of active substances or their source, Sativa, Indica (day/night), or hybrid intended for use 24 hours a day.

Do not drink wines or alcoholic beverages during the period of treatment with cannabis, especially in the beginning of treatment or upon changing the product/dosage. Drinking alcohol during the period of treatment with cannabis may augment various effects such as dizziness, coordination deficits, somnolence, loss of balance or impairment of the speed of response, thus impairing the ability to drive and operate machines and increasing the risk of falls and other accidents.

Do not use cannabis if you are pregnant, planning to become pregnant or breastfeeding.

Some of cannabis components pass into breast milk.

Use during pregnancy may lead to low neonatal weight.

Fertility - Sperm count and mobility may be decreased in men, and embryo implantation may be impaired in women.

If you are pregnant or breastfeeding, consult a doctor or pharmacist prior to using medicines.

Use of this product may impair alertness and cause somnolence, dizziness and several additional side effects (such as reduced concentration, impaired coordination and slowed responses), which may impair your ability to drive and/or operate heavy/dangerous machines and increase the risk of accidents.

Do not drive or operate dangerous machines during use or when active ingredients or their degradation products are present in the blood.

Then remove the inhalation mouthpiece from the lips and continue inhaling into the trachea and lungs. It is recommended to try to ensure inhalation for a measured period, gently and at constant intensity, for about 2 to 3 seconds.

Inhale calmly, not strongly and not rapidly. If you take strong and intense, large and too frequent inhalations, the flame will become very hot, and burning may be experienced in the respiratory tract, with cough and mucus.

If there is no combustion or if the combustion is not uniform, you may use the lighter very carefully, while the rolled cigarette is between the lips, and light the tip of the rolled cigarette while inhaling gently.

Recommended: an interval of about 30 to 60 seconds between inhalations

(according to the dosage of inhalations prescribed by the attending doctor).

4. Exhalation - After the measured inhalation, remove the cannabis product from the lips and exhale at controlled rate and intensity. Too rapid exhalation may also cause a sensation of burning, cough and mucus.

If you have to use the cannabis product again, place it on a clean ashtray until it is extinguished. Never extinguish it using a foreign matter, not even water.

Inhalation by evaporation: Using an evaporator extracting the active substances by heating without combustion. Follow the instructions for use of the evaporator.

Do not exceed the recommended dose.

Do not mix or add any other substance to the cannabis product content, including tobacco. The medical cannabis product content is adequate for use and any addition to it may interfere with the medical treatment efficacy.

If you have accidentally taken a higher dose, you may experience severe intoxication effects including dizziness, sleepiness, confusion, hallucinations (seeing or hearing things which do not exist) and believing in things which are not true (delusions), anxiety or paranoia (increased anxiety or fear), changes in the heart rate accompanied by low blood pressure (sensation of dizziness upon standing up).

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

If you forgot to take the product at the scheduled time, do not take a double dose to compensate for the forgotten dose! Take the next dose at the regular time and consult the doctor.

Adhere to the treatment as recommended by the doctor. Do not change the dosage without consulting the medical team.

Possession and place of use:

At the beginning of treatment, it is recommended to stay at home, in a relaxed atmosphere, in the presence of a responsible adult, with no pressure of time.

Possession and use of the product by the patient is allowed at any place not subject to a specific prohibition, provided that the patient carries the license with him and the product is in its original package, at a quantity not exceeding the cannabis quantity required for five days of consumption (which will be calculated according to the relative portion of the monthly quantity allowed in the license).

It is prohibited to use the product in the customs areas (such as an airport or a port); do not use it in the presence of minors.

It is prohibited to carry the product overseas.

During hospitalization, you may use the product only after receiving an approval from the hospital medical team, and in accordance with the team's instructions regarding the place of use and conditions of product possession.

5. How to store the product?

Prevent poisoning! To prevent poisoning, keep this product and any other medicine in a closed place, out of the reach and sight 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) which is stated on the package. The expiry date refers to the last day of that month.

Store the product in a dry and dark place, at a temperature below 25°C. It is important to close tightly to prevent penetration of light and moisture and to keep away from fire.

The product may be used for up to 6 months after opening the package, but no later than the expiry date indicated on the package.

Do not discard a cannabis product to the waste or wastewater. Ask the dispensing pharmacist how to destroy this product, which is no longer used, using measures that will help protect the environment.

Do not store in the same package with other medications/medicinal products.

6. Additional information

What the products looks like and contents of the pack:
Dried and packed cannabis inflorescences. Each package contains 10 grams.

Manufacturing, processing and packaging: Tikun Olam Production Ltd., Zilport Industrial Zone, 6 Hayatad.

Symbol legends
Below are symbols (and their meaning) which may appear on the packages of cannabis products.

1. Procedure / action

If this symbol is present on the product pack, it indicates that the cannabis underwent a procedure of microbial load reduction by "cold pasteurization" (irradiation with beta radiation)

If this symbol is present on the product pack, it indicates that the cannabis underwent a procedure of microbial load reduction by "cold pasteurization" (irradiation with gamma radiation)

If this symbol is present on the product pack, it indicates that the cannabis underwent a procedure of microbial load reduction by "cold plasma"

If this symbol is present on the product pack, it indicates that approved chemical agents were used during cannabis growing

If this symbol is present on the product pack, it indicates that biological pest control ("beneficial insects") was used during cannabis growing

If this symbol is present on the product pack, it indicates that only pesticides allowed for use in organic agriculture were used during cannabis growing

If this symbol is present on the product pack, it indicates that no pesticides were used during cannabis growing

Most common side effects:

- Sleepiness, tiredness or somnolence; mild to moderate dizziness – you may lie down until the feeling resolves. Somnolence and dizziness generally appear in the beginning of treatment or upon dosage elevation, and usually resolve after the body adapts to the product. You may need more sleeping hours in the beginning of treatment.

- Decrease in blood sugar levels, decrease in blood pressure, accelerated heart rate or strong heartbeats. To prevent the decrease in blood sugar levels, eat or drink something sweet (like a fruit or fruit juice) about 5 minutes prior to taking the product. In case of decrease in blood pressure, you can eat something salty or drink a caffeinated beverage. In patients taking anti-hypertensive or anti-diabetic medicines, the doctor may adjust the dosage of these medicines.

- Unstable heart rate, palpitations
- Increased appetite (especially craving for carbohydrates)
- Impaired coordination, instability
- Cognitive changes such as loss of short term memories, impairment of continuous thought and changes in the perception of time and space, impairment of concentration or judgment, and euphoria (sensation of being "high")
- Sensation of "heaviness" or floating, sensation of calmness or sensation of sharpened senses
- Mood swings, anxiety

- Cough and dry throat
- Dry and red eyes
- Headaches
- Local reactions in the oral cavity
- Abdominal pain or nausea if the product is inhaled on an empty stomach.

Side effects upon long term/chronic use:

- Impairment of cognitive capacity
- Dependence, addiction or abuse
- Chronic bronchitis or impaired lung function
- Decrease in prolactin, LH, FSH and GH hormones
- Electrolyte balance disorders. Caution is required in patients with renal failure
- Development or exacerbation of schizophrenia/psychosis.

Additional side effects of unknown frequency described in the literature:
Allergic reaction, cannabis arteritis, cardiac arrhythmias, heart failure, decreased body temperature and mobility, and even paralysis in rare cases, hypomania (loss of judgment and impulsive behavior).

Side effects usually resulting from overdose requiring special attention
High dosage of this product may, in certain cases, in predisposed people, cause a temporary outbreak of psychotic states, anxiety or hallucinations.

In addition, an overdose may cause sleepiness or severe dizziness or sedation, significant changes in blood pressure, heart rate, breathing rate or blood sugar levels, which may cause severe dizziness, nausea/vomiting, sweating, tremor, weakness, rapid pulse or heart rate, and even fainting. If possible, eat something sweet as soon as possible and lie down. Notify the medical team, who will guide you regarding dosage adjustment in the future.

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 the medical team.

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Store the product in a dry and dark place, at a temperature below 25°C. It is important to close tightly to prevent penetration of light and moisture and to keep away from fire.

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If this symbol is present on the product pack, it indicates that no pesticides were used during cannabis growing

אסמולחה של 2-1 אסטנשקל פי היום. בעד מא בקצב האבועים ימכן زیادة عدد مرات الاستنشاق دوريجاً حتى الوصول إلى التمتع المطلوب.

● **ملاحظات:** بعد تناول منتج تخنيق 3-4 مرات في اليوم تقريباً، من المحتمل تغيير عدد مرات الاستنشاق في كل تناول للتمتع وفقاً للحالة الفسيولوجية أو وفقاً لتكرار المواد المفلعة أو مستهدفة، مثل:النبيذ(الجاهز/ليل) أو هجين المعدة للاستعمال خلال كل ساعتين اليوم.

وصف المنتج:

1. **إسماک صفيح** - يجب إسماک منتج الكنايس عندما يكون كنتاج جاهزاً للاستعمال (سواء كان في أسطوانة أو في جهاز استنشاق) باليد الأيوية إنك (بالإنجليزية: في منطقة فوهة الاستنشاق (المعدفة)) بواسطة أسنمين، الإبه