



Medicinal cannabis

AUTHORISED IN LUXEMBOURG

INFORMATION FOR PATIENTS

Sante.lu



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la santé

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Introduction

The medicinal use of cannabis is an important milestone in the efforts to reduce the pain and suffering experienced by certain patients.

In Luxembourg, the prescription of medicinal cannabis has been authorised since 20 July 2018* and is currently in a pilot phase.

Its usage is strictly regulated and takes place in a medical setting with well-defined conditions (see below).

This booklet, drawn up by the Pharmacy and Medicines Division of the Health Directorate and validated by the Scientific Committee on Medicinal Cannabis, aims to present the overall context and the practical details of this pilot phase to supply medicinal cannabis.

* Law of 20 July 2018 amending the amended Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.
<http://legilux.public.lu/eli/etat/leg/loi/2018/07/20/a638/jo>

Grand-Ducal Regulation of 21 August 2018, amended by the Grand-Ducal Regulation of 10 October 2018 laying down the procedures for prescribing and accessing cannabis for medicinal purposes, as well as the content and duration of special training for medical specialists.

What is cannabis?

The cannabis plant (hemp) is essentially composed of leaves, flowers, stems and seeds. The term "cannabis" refers to the *Cannabis sativa* plant (the Latin name for hemp).

Cannabis is made up of several hundred different substances called (phyto) cannabinoids. The two best-known and most thoroughly studied compounds are:

- **THC** (delta-9-tetrahydrocannabinol)
- **CBD** (cannabidiol)

These two substances are mostly found in the flowers, also known as flowering tops, and to a lesser extent in the leaves.

The whole plant



The stems (fibres)



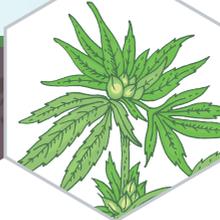
The seeds



The leaves



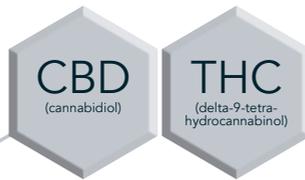
The flowers



Cannabinoids (THC and CBD)

Cannabinoids interact with the endocannabinoid system that is naturally present in the human body (see page 6). They can generate a variety of physiological effects.

CBD is the compound best known for its analgesic (pain-relief), anti-inflammatory and relaxing properties.



THC is the compound best known for its psychotropic effects.

NON-
PSYCHOACTIVE

PSYCHOACTIVE

THC and CBD are known for their therapeutic potential. THC is the compound responsible for the psychoactive effects of cannabis, whereas CBD doesn't seem to have any noticeable psychoactive effects.

The effects of cannabis are due to the actions of its cannabinoids on certain targets in the central nervous system or the peripheral tissues. These targets are receptors present throughout the human body (and among all vertebrate animals). Together with certain molecules and enzymes, these receptors make up the endocannabinoid system.

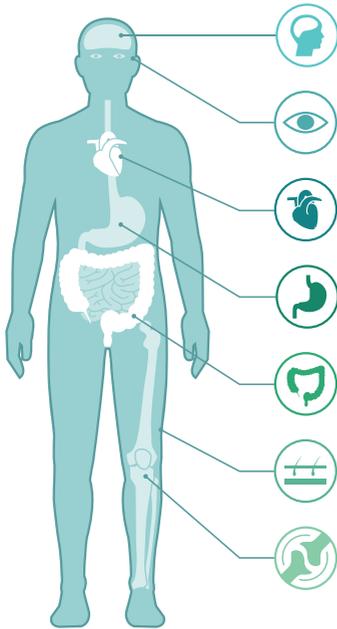
THC and CBD are regulated under the legislation on hemp and cannabis derivatives*.

Given that THC is considered as a drug, it is subject to narcotics regulations**.

* Law of 20 July 2018 amending the amended Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.

** Grand-Ducal Regulation of 4 March 1974 on certain toxic substances. Article 1 of the Grand-Ducal Regulation of 26 March 1974 establishing the list of narcotics.

The endocannabinoid system

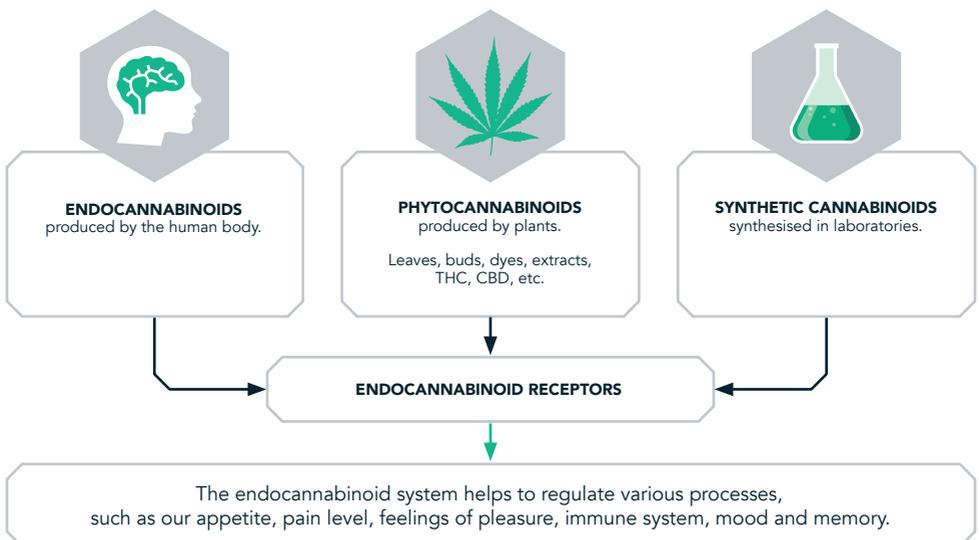


The purpose of the endocannabinoid system, present among humans and all vertebrate animals, is to respond to stressful situations (e.g. pains, inflammations, injuries, etc.) to help the body regain a balance. Endocannabinoid receptors can be found in the brain as well as in numerous peripheral tissues.

THC and CBD, as well as the other cannabinoids found in cannabis, interact with the human body's endocannabinoid system. However, the effects of this interaction may vary from one person to another.

There are three types of molecule which affect the endocannabinoid system: endocannabinoids produced by the human body, phytocannabinoids produced by plants, and synthetic cannabinoids of chemical origin.

How do cannabinoids work?

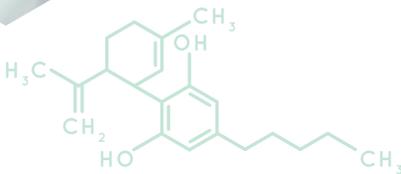


What's the difference between the medicinal and the recreational use of cannabis?



Cannabis contains the same active substances whether it is used for medicinal or recreational purposes.

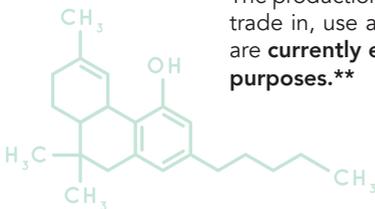
Medicinal cannabis is used for meeting specific health requirements. It is available on secure medical prescription extracted from a counterfoil book*, issued by a doctor who is certified by the Health Directorate. Medicinal cannabis also meets pre-defined quality and safety criteria. As such, the products in question are monitored by the health authorities.



Recreational cannabis is used without any medical reason and is not regulated. Its content, origin and composition are not guaranteed.

The 2018-2023 government programme provides for the drafting of legislation on recreational cannabis. Until this legislation has been published, non-medicinal cannabis remains prohibited in Luxembourg.

The production, manufacture, export, import, distribution of, trade in, use and possession of drugs, including cannabis, are **currently exclusively limited to medical and scientific purposes.****



* Grand-Ducal Regulation of 10 October 2018 amending the Grand-Ducal Regulation of 21 August 2018 laying down the procedures for prescribing and accessing cannabis for medicinal purposes, as well as the content and duration of special training for medical specialists...

** Luxembourg Health Code, "Drug abuse" section.

Medicinal cannabis: authorised products



The certified products which are authorised in Luxembourg and available on medical prescription are:

Dried flowering tops

with a defined THC and CBD content, of a standardised and certified quality.



Oil extracts

with a defined THC and CBD content (available from 2022).

There are three different chemotypes for dried flowering tops and oil extracts:

- THC dominant;
- CBD dominant;
- THC/CBD balanced, i.e. the two active ingredients, THC and CBD, are present in equal concentrations.

The prescriber is responsible for choosing the chemotype used for treatment with medicinal cannabis by taking the patient's medical history into account.



Medicinal products which contain THC or CBD and have a marketing authorisation

How to obtain medicinal cannabis and what are the conditions?

Conditions

Medicinal cannabis is authorised for the following conditions:

- **Serious chronic diseases** classified as long-term illnesses (affections de long durée – ALD) referred to in Article 19bis, paragraph 1 of the Luxembourg Social Security Code, at an advanced or terminal stage, causing chronic and debilitating pain which has not responded to the available therapies, or without conventional treatments available.
- **Cancerous diseases**, other than those referred to in the first indent, which are treated by chemotherapy, leading to nausea or vomiting.
- **Multiple sclerosis** with symptomatic muscle spasticity.

Who can benefit from medicinal cannabis?

Patients must meet **at least one of the following criteria:**

- Live in the Grand-Duchy of Luxembourg.
- Be a beneficiary of the Luxembourg health insurance system.
- Have Luxembourgish nationality.



Who can prescribe medicinal cannabis?

The product may **only be prescribed by a doctor** who is authorised to practise medicine in Luxembourg and has completed a **specific training course certified** by the Health Directorate*.

* If necessary, GPs can contact the Health Directorate to request a list of the practitioners who have completed this training course and are located nearby (subject to their permission).

How is medicinal cannabis dispensed?

- Medicinal cannabis can be obtained from hospital pharmacies in Luxembourg (see page 17).
- Medicinal cannabis is dispensed to patients free of charge upon presentation of a secure medical prescription extracted from a counterfoil book.



Is medicinal cannabis covered by the health system?

The products authorised by law are entirely covered by the Health Ministry as part of the pilot phase. Patients don't need to pay anything up front when collecting their prescription from one of the four hospital pharmacies authorised to dispense the products.



Risks associated with the consumption of medicinal cannabis

As is the case with any treatment, the use of medicinal cannabis entails risks, particularly for the following patients:

- Pregnant and/or breastfeeding women;
- Children, teenagers and young adults aged under 25: cannabis may have harmful effects on various aspects of their mental, neuronal and emotional development, depending on the age when the consumption begins as well as its duration and intensity;
- Patients with a history of addiction and/or consumption of substances such as alcohol, narcotics or other medicines;
- Patients with a history of mental illness (themselves or in their families);
- Patients with renal or hepatic insufficiency;
- Patients with an underlying heart condition;
- Elderly or bed-ridden patients, or people with reduced mobility.

Treatment with medicinal cannabis is not recommended for these groups of patients.

The benefits and risks of the treatment must be assessed by a doctor.

Adverse effects

The adverse effects of cannabis, particularly for products with a high THC content, vary a great deal from one person to another. The following effects have been reported: central nervous system disorders, such as light-headedness and dizziness, memory and attention disorders, psychiatric disorders, particularly mood swings, signs of depression, and in some cases hallucinations or psychotic disorders, food or gastrointestinal disorders and cardiovascular disorders, such as palpitations or an accelerated heartbeat.

Risk of addiction

There is a risk of abuse and/or addiction, particularly in the event of long-term consumption at high and frequent doses.

It's therefore important to watch out for any signs such as a lack of motivation, nervousness in the event of an insufficiency, a depressive state, becoming socially withdrawn, etc.

Additive effects and drug interactions

Certain adverse effects of cannabis can be accentuated in the presence of other medicines which have neurological effects (also known as central effects), such as: benzodiazepines, barbiturates, opioids, antihistamines, muscle relaxants and antiepileptic drugs.

You are strongly advised to refrain from consuming alcohol in combination with medicinal cannabis.

As things stand, very little scientific data has been published. Therefore, some of the potential interactions of cannabis with other substances are not yet known.



Effects on the ability to drive a vehicle

Taking cannabinoids may have substantial effects on your central nervous system, such as dizziness and/or drowsiness. Furthermore, your judgement and the performance of tasks requiring dexterity may be impaired. Due to an accumulation of THC in the body, **these effects may last for over 24 hours following the last consumption.**

Pursuant to the amended Law of 14 February 1955 on the regulation of traffic on all public roads, **“Any drivers of a vehicle or riders of an animal, as well as any pedestrians involved in an accident, who have one of the following substances in their body shall be subject to the penalties provided for in paragraph 1: THC [...] with a serum level equal to or greater than 1 ng/mL [...]”.**

A patient who needs to drive for personal or professional reasons (bus or lorry driver, machine operator, etc.) **must not be treated** with medicinal cannabis.

A patient treated with medicinal cannabis must not drive.



Age categories

The law does not lay down any age restriction regarding the prescription of medicinal cannabis. However, the Health Ministry advises against using medicinal cannabis for people aged under 25 unless the benefit/risk ratio is considered favourable by the doctor. As the brain's development does not reach full maturity until around 25 years of age, the neurological and psychiatric consequences of consuming cannabis before this age could be harmful and, in certain cases, irreversible.

Pharmacovigilance

To report an adverse event which is suspected to be associated with medicinal cannabis, contact your doctor or your pharmacist, who will contact the Pharmaceuticals and Medicines Division or the Regional Pharmacovigilance Centre in Nancy:

The Pharmaceuticals and Medicines Division
of the Health Directorate
pharmacovigilance@ms.etat.lu
Tél. (+352) 247-85592

Download the form to report any adverse effects from the website:
www.sante.public.lu:



or Le Centre Régional de Pharmacovigilance de Nancy
Bâtiment de Biologie Moléculaire
et de Biopathologie (BBB)
CHRU de Nancy
Hôpitaux de Brabois
Rue du Morvan
54511 VANDOEUVRE LES NANCY
CEDEX
crpv@chru-nancy.fr
Tél. (+33) 3 83 65 60 85 / 87

Transport and journeys

Cross-border workers

Cross-border workers who contribute to the National Health Fund (CNS) are eligible in accordance with the legislation in force. However, it is strictly prohibited to transport cannabis containing >0.2% THC in Europe and >1% THC in Switzerland.



Journeys (transport authorisation)

The transport of narcotics and/or psychotropic substances is governed by the Convention Implementing the Schengen Agreement. **Any patients who wish to travel while transporting medicinal cannabis or any other medicinal drug should contact the countries crossed in transit and the destination countries to seek information on the legislation in force.** If necessary, the Health Directorate can issue a certificate based on a medical prescription for a **maximum duration of 30 days** if the person is travelling to a State signatory to the Convention Implementing the Schengen Agreement. The Health Directorate will issue or authenticate the certificate based on a medical prescription. Each narcotic or psychotropic substance prescribed requires a separate certificate.

Patients are invited to contact their doctor to fill in the certificate which can be downloaded from sante.lu:



Dosage

The most effective dose that is best tolerated by the patient may vary a great deal from one person to the next. The dosage therefore needs to be established by the doctor for each patient.

The dosage remains highly individualised and is essentially based on titration, which means gradually increasing the doses until the most effective and best tolerated dosage is reached. **The treatment should begin at very small doses and must be stopped in the event of any major adverse effects.**

This is particularly important for patients who are starting their first therapy using medicinal cannabis.

How to use flowering tops

There are various methods for using the flowering tops that are available in Luxembourg.

Examples of two vaporisers with CE marking:



MIGHTY MEDIC
(pharmaceutical
registration number:
13903413)



VOLCANO MEDIC
(pharmaceutical
registration number:
13903436)



By vapourisation

Inhalation is the most widely used consumption method. The effects can be felt quickly: most consumers feel the effects within a few minutes of inhalation. Patients who wish to inhale medicinal cannabis need to purchase a vaporiser that can reach 180°C.

When vaporising cannabis, the dose needed to obtain the therapeutic effects and to avoid undesirable effects is influenced by the depth of inhalation, the length of time that each breath is held as well as the number and frequency of breaths. Patients are recommended to vaporise the product slowly and gradually, and to stop if they start to feel any adverse effects such as disorientation, dizziness, agitation, ataxia (coordination problems), anxiety, tachycardia and orthostatic hypotension, hallucinations or psychosis.



By infusion

To prepare a herbal tea using flowering tops, you may first need to activate them*. This decarboxylates (activates) the active ingredients. The process involves heating up the flowering tops in the oven (for 45 minutes at 130°C or 10 minutes at 160°C). Then, as THC dissolves in lipids, you need to add a fatty substance (e.g. vegetable oil, butter, crème fraîche, etc.) for around 15 minutes. This extracts the cannabinoids from the plant and improves the body's ability to absorb the THC.

For doses administered orally, the effects take 30 to 60 minutes to be felt, or even longer following ingestion. You therefore need to consume small doses at the start of your treatment.

* Hospital pharmacists will let you know if the products available need to be activated as such, and the prescribing doctor will provide you with a preparation protocol.

Who can dispense medicinal cannabis?

With a specific prescription, patients can collect their dose of medicinal cannabis free of charge from one of the **four hospital pharmacies, according to the terms specified by the doctor on the prescription.**

Patients must observe the hospital pharmacies' dispensing times.

List of the hospital pharmacies which dispense medicinal cannabis on prescription.

Name of pharmacy	Contact	Dispensing days	Opening times
CHL - Luxembourg Centre Hospitalier de Luxembourg	44 11 46 23 pharmaciens@chl.lu	Monday > Friday	8:00 a.m. > 1:00 p.m. 2:00 > 4:30 p.m.
HRS - Luxembourg Hôpitaux Robert Schuman (Only at the Kirchberg site for the time being)	24 68 33 52 retrocession@ hopitauxschuman.lu	Monday > Friday	9:00 a.m. > 3:00 p.m.
CHEM - Esch-sur-Alzette Centre Hospitalier Emile Mayrisch	57 11 81 000	By appointment	1:00 > 4:00 p.m.
CHDN - Ettelbruck Centre Hospitalier du Nord	81 66 31 55 pharmaciens@chdn.lu	Monday > Friday	2:00 > 3:30 p.m.

Important: patients must check the dispensing procedures of the hospital pharmacy that they wish to go to (see table above). They must also go to the hospital pharmacy **within 60 days of the prescription date.** If the items to be dispensed are split, all items on the same prescription are to be dispensed by the same hospital pharmacy.

Glossary

Cannabinoids: active chemical substances contained in cannabis.

Cannabis decarboxylation: the action of heating up the flowering tops of cannabis to obtain active THC.

Cannabis sativa: the Latin name for hemp.

CBD: cannabidiol (CBD) is the cannabinoid best known for its analgesic (pain-relief), anti-inflammatory and relaxing properties. It does not appear to have any psychoactive effects.

Endocannabinoid receptors: receptors found in the brain as well as in numerous peripheral tissues. They belong to the endocannabinoid system.

Endocannabinoid system: system present among humans and all vertebrate animals. Its function is to respond to stressful situations (e.g. pains, inflammations, injuries, etc.) to help the body regain a balance, also called homeostasis.

Endocannabinoids: cannabinoids produced by the brain. Their effects are mainly due to their link to cannabinoid receptors.

Flowering tops: tops of a plant when in flower.

Hemp: green plant (also known as cannabis) containing less than 0.3% THC (in accordance with Luxembourgish regulations).

MA: marketing authorisation

Muscle spasticity: increase in muscle tone leading to constant muscle stiffness, spasms or contractions, or both.

Narcotics: psychoactive substances which, if misused, may lead to drug addiction or abuse. At international level, narcotic drugs feature on lists created by United Nations conventions. The objective is to restrict the use of narcotics to medical and scientific purposes and to control their use to prevent any abuse or diversion to illicit trafficking.

Oil extract: mixture of vegetable extracts with oil.

Phytocannabinoids: cannabinoids synthesised by plants.

Psychoactive effect: effect of a chemical substance that influences mental activity.

Synthetic cannabinoids: cannabinoids of chemical origin.

THC: abbreviation of delta-9-tetrahydrocannabinol (THC). This is the most documented cannabinoid. THC is responsible for psychoactive effects.

Notes

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