

**Checklist for applications for an exemption to prescribe Dronabinol solution 2.5%
OR Cannabis tincture normalized (10 mg THC/ml)
OR Cannabis oil normalized (10 mg THC/ml)**

For granting a special permit for Marinol® or Dronabinol solution (or cannabis tincture or cannabis oil) to patients in accordance with article 8, paragraph 5 of the Federal Law on Narcotic Drugs of October 3, 1951 (BetmG), an application with the following informations and documents needs to be submitted to the Federal Health Office (see address below).

- Name, first name, date of birth and address of the patient
- Indication
- Indication of the drugs used to date for the treatment of this specific disease
- Intended delivery form (dronabinol solution, cannabis tincture or cannabis oil) and intended dosage
- Provisional treatment duration
- Written consent of the patient for treatment with dronabinol / cannabis tincture / cannabis oil
- Written confirmation from the responsible physician to take full responsibility for all consequences of his prescription of dronabinol, cannabis tincture or cannabis oil
- written approval from the responsible physician to prepare an interim report on the progress of the treatment every 6 months, as well as to draw up a final report and to send these reports to the Federal Office of Public Health
- A detailed description of the type of patient monitoring and care (at the start and after stabilization)
- Intended supplier: Bahnhofapotheke Langnau AG, Dorfstr. 2, 3550 Langnau
- Provisional flow of logistics for delivering the drug to the patient (direct delivery to the patient, direct delivery by the responsible physician or delivery by a public pharmacy or hospital pharmacy)
- If the medication is to be delivered from a public pharmacy / hospital pharmacy: indicate the name and address of the pharmacy
- Information on the nature of the financing of the therapy, since the costs do not necessarily have to be covered by the health insurance fund

Address for submission of the exemption (all applications must be submitted in writing, via regular post):

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Nationale Präventionsprogramme NPP
Schwarzenburgstrasse 157
3003 Bern

Tel. +41 58 463 87 90

Information for the delivery of dronabinol solution 2.5%
OR Cannabis tincture (10 mg THC/ml)
OR Cannabis oil (10 mg THC/ml)

Application / request

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Nationale Präventionsprogramme NPP
Schwarzenburgstrasse 157
3003 Bern

Delivery

The prescribed Dronabinol solution (or Cannabis tincture or Cannabis oil) is "registered mail" and will be delivered at the

- a) address of the physician or
- b) delivered to a pharmacy or
- c) directly to the patient (with the statement "personal signature")

Billing

Two options:

- a) amount paid by patient or health insurance
Normal selling price
- b) amount paid by physician or pharmacy
Normal selling price minus 10% discount

Dronabinol solution (or Cannabis tincture or Cannabis oil) is not a standard benefit of health insurance. Please clarify in advance with the health insurance (provide cover), whether the drug will be taken on charge or not.

Delivery time

The dronabinol solution, Cannabis tincture or Cannabis oil will be delivered within 1-3 days once we are in possession of:

- Copy of the decision of the BAG (E.g. by fax)
- Narcotic prescription (original version), including quantity and dosage instructions

If a longer duration of the treatment is to be foreseen, and the amount needed is difficult to be estimated, the narcotic drug prescription can be determined for a certain period of time (E.g. valid for 2 months, but for maximum 3 months). Otherwise, for each new order it takes a new narcotic prescription (same handling like other drugs, which are under narcotic law)

For questions:

Bahnhof Apotheke Langnau AG
Dr. M. + B. Fankhauser
Dorfstrasse 2
3550 Langnau

Tel. 034 402 12 55 (press button 2 after the recorded message)
Fax 034 402 25 35
Mail: fankhauser@cannabis-med.ch

Dronabinol solution 2,5 % (NRF 22.8.)

Dronabinol is the international non-proprietary name for Delta-9-tetrahydrocannabinol (THC)

Package sizes / prices

Dropper bottle	5g (equivalent to 125 mg Dronabinol)	Fr. 220.00	1 mg Dronabinol costs Fr. 1.76
	10g (equivalent to 250 mg Dronabinol)	Fr. 425.00	1 mg Dronabinol costs Fr. 1.70
	20g (equivalent to 500 mg Dronabinol)	Fr. 825.00	1 mg Dronabinol costs Fr. 1.65
	40g (equivalent to 1000 mg Dronabinol)	Fr. 1600.00	1 mg Dronabinol costs Fr. 1.60

Daily treatment costs (based on 10 g bottle)

Daily intake of 5mg	Fr. 8.50
Daily intake of 10 mg	Fr. 17.00
Daily intake of 20 mg	Fr. 34.00

36 drops correspond an average of 1.0 g solution.
360 drops correspond an average of 10.0 g solution.

<u>Conversion Table (mg drops accordingly)</u>		
Note: special, standardized droplet		
1 drop	corresponds to	≈ 0.7 mg THC
3-4 drops	correspond to	≈ 2,5 mg THC
7 drops	correspond to	≈ 5,0 mg THC
10 drops	correspond to	≈ 7,0 mg THC
15 drops	correspond to	≈ 10,0 mg THC
20 drops	correspond to	≈ 14,0 mg THC
36 drops (= 1 g of sol.)	corresp. to	≈ 25,0 mg THC
(Density of dronabinol solution 2.5%: about 0.95 g / cm ³)		

Practical example:	3 x daily 2.5 mg Dronabinol	(=3 x daily 3-4 drops)
	3 x daily 5.0 mg Dronabinol	(=3 x daily 7 drops)
	3 x daily 10.0 mg Dronabinol	(=3 x daily 15 drops)

Dosage and administration

The dosage is individual and determined by the physician. Depending on the indication, the daily dose can vary from 2.5 mg to 30 mg Dronabinol. In exceptional cases, the dosage might even be higher.

The oily droplets are preferably taken with fatty food (for example, drop on a cookie or drop in some dressing oil). When counting the drops position the bottle in a vertical axis (even).

Durability/Stability

From the date of manufacture, the medicine is stable for 6 months. The solution is conserved with the natural preservative ascorbyl palmitate (0.05%). In rare cases a slight reddening of the solution may occur, which has no effect on effectiveness and durability. The solution should be stored at room temperature.

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Cannabis tincture normalized (about 10 mg THC / ml)

Cannabis sativa extractum fluidum normatum Charge Nr. 1634 1901

Cannabis tincture normalized "standardized", on

Stand: Januar 2017

- 11 mg THC total/g
- 22 mg CBD total/g

Package sizes / prices

Veral bottle, brown (with separate pipette)

10 ml (= 9.1 g)	corresponds to approx. 100 mg THC	CHF 120.00	1 mg THC costs CHF 1.20
20 ml (= 18.2 g)	corresponds to approx. 200 mg THC	CHF 230.00	1 mg THC costs CHF 1.15
50 ml (= 45.5 g)	corresponds to approx. 500 mg THC	CHF 550.00	1 mg THC costs CHF 1.10

(Density of ethanolic tincture (ethanol content: 80% V / V): 0.8784 g / cm³ at 20 ° C)

Day-therapy costs (based on 20 ml bottle)

Daily dose 5 mg	CHF 5.75
Daily dose 10 mg	CHF 11.50

Conversion table (drop corresponding to mg), dropper pipette, Art. 14.014.00

Drop count	Corresponds to	THC (mg)	CBD (mg)
1 drop of tincture	corresponds to	0.29 mg	
<u>3-4 drops of tincture</u>	correspond to	0.87 mg (<u>≈ ca. 1 mg</u>)	<u>(≈ ca. 2 mg) CBD</u>
<u>9 drops of tincture</u>	correspond to	2.61 mg (<u>≈ ca. 2.5mg</u>)	<u>(≈ ca. 5 mg) CBD</u>
10 drops of tincture	correspond to	2.9 mg	
<u>17 drops of tincture</u>	correspond to	4.93 mg (<u>≈ ca. 5 mg</u>)	<u>(≈ ca. 10 mg) CBD</u>
<u>34 drops of tincture</u>	correspond to	9.86 mg (<u>≈ ca. 10 mg</u>)	<u>(≈ ca. 20 mg) CBD</u>
350 drops (10 ml) of tinct.	correspond to	101.5 mg	

The number of drops per bottle can vary slightly (depending on the inclination of the pipette and temperature)
1 drop of the tincture has the weight of 0.0260 g, which means that this contains 0.29 mg THC

Dosage

The dosage is individual and is determined by the physician. Depending on the indication, the daily dose may range from 2.5 mg to 30 mg THC.

Standard dosage: 2 to 3 x daily 2.5 mg (corresponds to 2 to 3 x daily 8-9 drops).

The drops are taken with little water.

Durability

Expiry date: is indicated on the dispensing bottle. Alcohol: 74.0% (m / m) ≈ 80% (v / v).

The cannabis tincture should be stored in the refrigerator (2-8 ° C) in order to prevent loss of efficacy.

The tincture must be protected from light (in a brown medicinal bottle) and must be well closed after use.

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Cannabis oil normalized (about 10 mg THC / ml)

Cannabis sativa extractum oleatum

Charge Nr. 1645 3901

Cannabis oil normalized "standardized", on

Stand: Januar 2017

- 11.0 mg THC total/g
- 24.0 mg CBD total/g

Package sizes / prices

Aponorm bottle, brown (with separate pipette)

10 ml (= 9.23 g)	corresponds to approx. 110.7 mg THC	CHF 165.00	1 mg THC costs CHF 1.50
20 ml (= 18.36 g)	corresponds to approx. 220.4 mg THC	CHF 320.00	1 mg THC costs CHF 1.45
50 ml (= 46.15 g)	corresponds to approx. 553.8 mg THC	CHF 775.00	1 mg THC costs CHF 1.40

(Density of the oily solution: 0.9291 g / cm³ at 20 ° C)

Day-therapy costs (based on 20 ml bottle)

Daily dose 5 mg CHF 7.25

Daily dose 10 mg CHF 14.50

1 drop of oil	ca. 0.033 g	corresponds to	0.40 mg THC	0.86 mg CBD
3 drops of oil	0.1 g	correspond to	1.2 mg THC	2.6 mg CBD
6 drops of oil	0.2 g	correspond to	2.5 mg THC	5.2 mg CBD
12-13 drops of oil	0.4 g	correspond to	5.0 mg THC	11.0 mg CBD
25 drops of oil	0.8 g	correspond to	10.0 mg THC	21.5 mg CBD
30 drops of oil	1.0 g	correspond to	12.0 mg THC	26.0 mg CBD
277 drops (10 ml) of oil	9.23 g	correspond to	111 mg THC	238 mg CBD

The number of drops per bottle can vary slightly (depending on the inclination of the pipette and temperature)

Dosage

The dosage is individual and determined by the physician. Depending on the indication, the daily dose can vary from 2.5 mg to 30 mg Dronabinol. In exceptional cases, the dosage might even be higher.

The oily droplets are preferably taken with fatty food (for example, drop on a cookie or drop in some dressing oil). When counting the drops, position the bottle in a vertical axis (even).

Durability

Expiry date: Is indicated on the dispensing bottle.

As a carrier oil, a biological hemp seed oil is used which is stabilized with the natural preservative ascorbyl palmitate (0.05%).

The solution is stable for 6 months. It is recommended to keep the oil in the refrigerator.

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