

# PACKAGE INSERT: TINCTURE



## 1:1 TINCTURE

PRODUCT	PER BOTTLE	PER DOSE	TOTAL DOSES
500MG BOTTLE	250MG THC, 250MG CBD	0.5MG THC, 0.5 CBD	500

1 Dose = 1 Drop

**Cutting Ingredients:** MCT Oil & Flavoring

### INTRODUCTION

This leaflet provides a summary of information about 1:1 Tincture. Please read it and keep it with your medicines in case you need to look at it again. Ask your doctor if you have any questions.

1:1 Tincture contains delta-9 tetrahydrocannabinol (THC) and cannabidiol (CBD) extracted from the Cannabis Sativa L. (marijuana) plant. THC is a psychoactive phytocannabinoid which works on the body's internal endocannabinoid system. Cannabidiol is a non-psychoactive phytocannabinoid which works on the body's internal endocannabinoid system.

### IMPORTANT

YOUR DOCTOR HAS RECOMMENDED THIS DRUG FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT.

KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS.

If a child puts cartridge contents in his or her mouth or swallows this drug take the medicine away from the child and contact a poison control center immediately, or contact a doctor immediately.

Do not drive a car or operate machinery until you know how this drug affects you. While taking this drug, do not drink alcohol or take other drugs that have an effect on the central nervous system (such as sleeping pills or antidepressants).

Unless advised by your doctor, do not use this drug if you are pregnant or nursing.

### CLINICAL PHARMACOLOGY

1:1 Tincture contains a 1:1 mixture of purified delta-9-tetrahydrocannabinol (THC) and cannabidiol from naturally grown, pesticide-free Cannabis Sativa plants. THC is a phytocannabinoid (a plant-based cannabinoid), which mimics the effects of internally produced cannabinoids made by the brain and other parts of the human body. It acts on the endocannabinoid system to regulate pain and many other processes in the body. THC stimulates the CB1 receptors, which are located throughout the brain and to some degree the rest of the body. When taken by mouth about 50% of the THC is changed in the liver to 11-OHdelta-9-THC, which has a stronger effect than delta-9-THC.

THC has "psychoactive" effects on humans, sometimes called a "high." This affect varies by the person, the dose taken, and the type of THC used (oral, inhaled, topical). A variety of potential effects can occur, ranging from relaxation, euphoria, and enhanced enjoyment of food to anxiety or paranoia.

With oral ingestion of THC the onset of action is delayed compared to inhalation. An effect is usually felt in 1-2 hours after consuming the medication and may last 4-6 hours.

THC regulates the perception of pain through a complex neurological modulation system in the spinal cord, cerebral cortex, hypothalamus, and other portions of the brain. It also has anti-inflammatory effects, and effects on the gastrointestinal and musculoskeletal systems. THC has anti-nausea and anti-vomiting effects.

THC can cause psychosis, anxiety, and sedation. Lethal overdose in humans has not been reported as THC spares the autonomic nervous system (CB1 receptors are absent in brainstem).

CBD is a phytocannabinoid (a plant-based cannabinoid), which mimics the effects of internally produced cannabinoids made by the brain and other parts of the human body. It acts on the endocannabinoid system to regulate pain, anxiety, reduce seizures and inflammation, and many other processes in the body. CBD also reduces the psychoactive effect of THC (tetrahydrocannabinol). This is called "the entourage effect." CBD indirectly increases the effects of the body's internally produced endocannabinoids.

Unlike THC, CBD does not have a psychoactive effect or produce a "high." When taken with THC, it may lessen the psychoactive effect of the THC.

With oral ingestion of CBD the onset of action is delayed compared to inhalation. An effect is usually felt in 1-2 hours after consuming the medication and may last 4-6 hours. Side effects are not common with CBD. CBD can cause aggravation of anxiety or depression, dry mouth, dizziness, or feeling faint. At low doses it may cause insomnia but at high doses may cause sleepiness. Lethal overdose in humans has not been reported as CBD does not affect the breathing centers in the brainstem.

Because of individual variability in responses, each patient must start at a low dose, and increase the dose very slowly, under a physician's guidance.

### INDICATIONS AND USE

1:1 Tincture is indicated in cancer, glaucoma, epilepsy, HIV/AIDS, hepatitis C, ALS, Crohn's disease, Parkinson's disease, and other conditions as determined by your physician. It also may be useful in those with terminal illness.

### DOSAGE AND ADMINISTRATION

The most important consideration in dosage and administration is to start at a very low dose and to increase the dose slowly ("titration") to determine the correct dose for you and to minimize side effects. People with no prior experience using marijuana ("cannabis naïve" patients) should be especially careful to follow this guidance.

When taking 1:1 Tincture the patient will usually feel an effect within 1-2 hours after ingestions and the effect will usually last 4-6 hours, or longer.

Medical cannabis can have a "biphasic effect," where at low doses there may be one effect (wakefulness) and at higher doses the opposite effect (sleepiness). That is why "titration" is so important.

One drop, or multiple drops, 1:1 Tincture should be placed inside the mouth between the cheek and gums or on the tongue and allowed to be absorbed.

The starting dose for 1:1 for most conditions ranges from 5mg to 10mg per day and the total dose usually taken ranges from 100mg to 300mg per day.

### CONTRAINDICATIONS

Cannabis products should not be taken by patients known to be allergic to cannabis.

There is some theoretical risk of suppression of the immune system based on laboratory studies, though this effect has not been proven in clinical studies.

### WARNINGS AND PRECAUTIONS

Be sure to tell your doctor if you:

- Have or had heart disorders because of occasional low blood pressure, possible high blood pressure, fainting, or rapid heart rate;
- Have current or a history of drug abuse;
- Have current or a history of alcohol abuse;
- Have or had mental health problems (mania, depression, bipolar, schizophrenia);
- Have a history of epilepsy, seizure disorder, and/or seizure-like activity;
- Have allergies to drugs;
- Are pregnant or nursing, or become pregnant.

If you become pregnant while taking CBD Tincture stop using it until you have talked to your doctor.

CBD Tincture should be used with caution in children because there are few studies in children. THC use in teenagers may have adverse effects on brain development but no studies have confirmed this concern with CBD use. The potential benefits in a teenager should be considered in light of the potential harms.

CBD Tincture should be used with caution in older patients because there are few studies specifically in older persons.

CBD Tincture can theoretically interact with other medications or grapefruit, and may increase the effect of other drugs. You should not take CBD with grapefruit or grapefruit juice. Tell your doctor if you are taking any other prescription or nonprescription medicines.

### ADVERSE REACTIONS

Cardiovascular: Palpitations, tachycardia, vasodilation/facial flush, hypotension (low blood pressure).

- Digestive: Dry mouth, abdominal pain, nausea, vomiting, anorexia, hepatic enzyme elevation, diarrhea, fecal incontinence.
- Nervous system: Euphoria, drowsiness, memory loss, anxiety/nervousness, poor balance, confusion, depersonalization, dizziness, euphoria, hallucinations, paranoid reaction, somnolence, abnormal thinking, depression, nightmares, speech difficulties, tinnitus.
- Musculoskeletal: Myalgias.
- Skin and Appendages: Flushing, sweating.
- Special senses: Conjunctivitis, vision difficulties.
- Body as a whole: Chills, headache, fatigue.
- Respiratory: Cough, rhinitis, sinusitis.

# PACKAGE INSERT: TINCTURE



## CBD TINCTURE

PRODUCT	PER BOTTLE	PER DOSE	TOTAL DOSES
500MG BOTTLE	500MG CBD, <15 THC	1MG CBD, <0.03 CBD	500

**1 Dose = 1 Drop**

**Cutting Ingredients: MCT Oil & Flavoring**

### INTRODUCTION

This leaflet provides a summary of information about CBD Tincture. Please read it and keep it with your medicines in case you need to look at it again. Ask your doctor if you have any questions.

CBD Tincture contains cannabidiol, extracted from the cannabis (marijuana) plant. Cannabidiol is a non-psychoactive phytocannabinoid which works on the body's internal endocannabinoid system.

### IMPORTANT

**YOUR DOCTOR HAS RECOMMENDED THIS DRUG FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT.**

**KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS.**

If a child puts product in his or her mouth or swallows this drug take the medicine away from the child and contact a poison control center immediately, or contact a doctor immediately.

Do not drive a car or operate machinery until you know how this drug affects you. While taking this drug, do not drink alcohol, or take other drugs that have an effect on the central nervous system (such as sleeping pills or antidepressants).

Unless advised by your doctor, do not use this drug if you are pregnant or nursing.

### CLINICAL PHARMACOLOGY

CBD Tincture contains purified cannabidiol from naturally grown, pesticide-free Cannabis Sativa plants. CBD is a phytocannabinoid (a plant-based cannabinoid), which mimics the effects of internally produced cannabinoids made by the brain and other parts of the human body. It acts on the endocannabinoid system to regulate pain, anxiety, reduce seizures and inflammation, and many other processes in the body. CBD also reduces the psychoactive effect of THC (tetrahydrocannabinol). This is called the "entourage effect." CBD indirectly increases the effects of the body's internally produced endocannabinoids.

Unlike THC, CBD does not have a psychoactive effect or produce a "high." When taken with THC, it may lessen the psychoactive effect of the THC.

With oral ingestion of CBD the onset of action is delayed compared to inhalation. An effect is usually felt in 1-2 hours after consuming the medication and may last 4-6 hours.

Side effects are not common with CBD. CBD can cause aggravation of anxiety or depression, dry mouth, dizziness, or feeling faint. At low doses it may cause insomnia but at high doses may cause sleepiness. Lethal overdose in humans has not been reported as CBD does not affect the breathing centers in the brainstem.

Because of individual variability in responses, each patient must start at a low dose, and increase the dose very slowly, under a physician's guidance.

### INDICATIONS AND USE

CBD Tincture is indicated in cancer (multiple symptoms such as appetite loss, insomnia, anxiety, nausea and vomiting), seizures (when typical medications have failed), and muscle spasticity. It may be especially helpful in patients who find medical cannabis helpful but do not tolerate or wish to avoid the psychoactive effects of THC.

### DOSAGE AND ADMINISTRATION

The most important consideration in dosage and administration is to start at a very low dose and to increase the dose slowly ("titration") to determine the correct dose for you and to minimize side effects. People with no prior experience using marijuana ("cannabis naïve" patients) should be especially careful to follow this guidance.

When taking CBD Tincture the patient will usually feel an effect within 1-2 hours after ingestions and the effect will usually last 4-6 hours, or longer.

Medical cannabis can have a "biphasic effect," where at low doses there may be one effect (wakefulness) and at higher doses the opposite effect (sleepiness). That is why "titration" is so important.

One drop, or multiple drops, CBD Tincture should be placed inside the mouth between the cheek and gums or on the tongue and allowed to be absorbed.

The starting dose for CBD for most conditions ranges from 5mg to 10mg per day and the total dose usually taken ranges from 100mg to 300mg per day.

### CONTRAINDICATIONS

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CBD Tincture should be used with caution in older patients because there are few studies specifically in older persons.

CBD Tincture can theoretically interact with other medications or grapefruit, and may increase the effect of other drugs. You should not take CBD with grapefruit or grapefruit juice. Tell your doctor if you are taking any other prescription or nonprescription medicines.

### ADVERSE REACTIONS

CBD has been well-tolerated in most clinical studies. Some adverse effects reported include dry mouth, hypotension (low blood pressure), orthostatic hypotension (blood pressure falls when standing up), psychomotor slowing (slow movements or thinking), sedation, and somnolence (sleepiness).