

# PACKAGE INSERT: TRUINCTURE DROPS



## TRUINCTURE DROPS

TYPE	PER BOTTLE	PER DOSE	TOTAL DOSES
HYBRID, INDICA, SATIVA	100MG THC, <1MG CBD	10MG THC, <1MG CBD	10
1:1	50MG THC, 50MG CBD	5MG THC, 5MG CBD	10
CBD	<1MG THC, 100MG CBD	<1MG THC, 10MG CBD	10

### 1 Dose = 1 Lozenge

**Cutting Ingredients:** Isomalt, Water, Cannabis Oil, Polysorbate 80, Coconut oil, Soy Lecithin, Sorbic Acid, Sodium Benzoate, Vitamin E Oil, Acesulfame Potassium, Natural and Artificial Flavor, Natural Taste Modifiers

**Food Allergy Warning:** Contains Soy

## INTRODUCTION

This leaflet provides a summary of information about **TruTincture Drops**. 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.

**TruTincture Drops** is derived from the Cannabis sativa plant (marijuana) and contains delta-9 tetrahydrocannabinol (delta-9 THC). Delta-9 THC is a 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 the contents of this container 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

**TruTincture Drops** is derived 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.

THC has "psychoactive" effects on humans, sometimes called a "high." This effect varies by person, dose taken, and 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.

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 has not been reported in humans as there are no cannabinoid receptors 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

**TruTincture Drops** is indicated in "Debilitating Medical Conditions" - cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis or other conditions for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient. It is also indicated in the palliative care treatment of terminal illness (e.g. pain, appetite loss, weight loss, sleep disturbances, spasticity, and anxiety).

## 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 naive" patients) should be especially careful to follow this guidance.

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

When taking **TruTincture Drops** the patient will usually feel an effect in minutes after ingestion and a "peak" effect in 30 minutes. The effect will usually last 1 – 4 hours, or longer depending on dosage used.

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

## CONTRAINDICATIONS

Cannabis products are contraindicated in patients known to be allergic to cannabis.

Relative contraindications include coronary artery disease, hypotension, drug abuse, alcohol abuse, mania, depression, bipolar, schizophrenia, or a prior negative reaction to cannabis.

## 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 using THC, stop using it until you have talked to your doctor.

**TruTincture Drops** 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. The potential benefits in a teenager should be considered in light of the potential harms.

**TruTincture Drops** should be used with caution in older patients because they may be more sensitive to the neurological, psychoactive, and low blood pressure effects of the drug.

**TruTincture Drops** can dangerously interact with alcohol and with other drugs that have an effect on the central nervous system (such as Valium, Librium, Xanax, Seconal, Nembutal, or Phenobarbital).

Do not drive or operate machinery until you are sure how **TruTincture Drops** affects you and you are able to perform safely.

You may experience changes in mood or have other effects when first taking **TruTincture Drops**. Be sure that there is a responsible person nearby when you first take **TruTincture Drops** or when there is an adjustment in your dose.

Tell your doctor if you are taking any other prescription or nonprescription medicines.

Do not smoke marijuana while using THC. This can cause increased side effects.

## 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.