

PACKAGE INSERT: TRUCHOCOLATE



TRUCHOCOLATE

PRODUCT	PER PACKAGE	DOSE PER PIECE	TOTAL DOSES
THC BAR	100MG THC, <1MG CBD	10MG THC, <1MG CBD	10
1:1:1 BAR	33.3MG Δ-9 THC, 33.3MG Δ-8 THC, 33.3MG CBD	3.3MG Δ-9 THC, 3.3MG Δ-8 THC, 3.3MG CBD	10
DROPS	150MG THC, <1MG CBD	10MG THC, <1MG CBD	15

Product Types: Hybrid, Indica, Sativa, Ratio

TruChocolate Bar Ingredients: Distillate Cannabis Oil (10mg THC per square), Dark and Milk Chocolates (Chocolate Liquor, Sugar, Cocoa Butter, Anhydrous Milk Fat, Milk, Soy Lecithin, Vanilla)

Dark Chocolate with Mint TruChocolate Bar Ingredients: Distillate Cannabis Oil (10mg THC per square), Dark Chocolate (Sugar, Chocolate (Processed with Alkali), Cocoa Butter, Milkfat, Soy Lecithin, Vanilla), Mint Oil (Sunflower Oil, Natural Flavor)

Ratio TruChocolate Bar Ingredients: Distillate Cannabis Oil (3.3mg CBD, 3.3mg Delta 8 THC, and 3.3mg Delta 9 THC per square), Dark and Milk Chocolates (Chocolate Liquor, Sugar, Cocoa Butter, Anhydrous Milk Fat, Milk, Soy Lecithin, Vanilla)

TruChocolate Drops Ingredients: Distillate Cannabis Oil (10mg THC per Piece), Dark Chocolate (Sugar, Chocolate (Processed with Alkali), Cocoa Butter, Milkfat, Soy Lecithin, Vanilla)

Allergen Information: Contains Milk and Soy

ALL DOSAGE AMOUNTS SUBJECT TO VARY BASED ON INDIVIDUAL USE.

INTRODUCTION

This leaflet provides a summary of information about **TruChocolate**. 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.

TruChocolate contain delta-9 tetrahydrocannabinol (delta-9 THC) extracted from the Cannabis Sativa L. (marijuana) plant. 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 the the container in his or her mouth or swallows this drug, take the medicine away from the child and contact a poison control center and/or 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

TruChocolate contain purified delta-9-tetrahydrocannabinol (THC) 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-OH-delta-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).

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

TruChocolate are 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.

When taking **TruChocolate** the patient will usually feel an effect within 1-2 hours after ingestion 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 (like relaxation) and at higher doses the opposite effect (like anxiety). That is why "titration" is so important.

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

CONTRAINDICATIONS

All 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 taking **TruChocolate**, stop using it until you have talked to your doctor.

TruChocolate should be used with caution in children because there are few studies on THC use with 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.

TruChocolate 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.

TruChocolate 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 **TruChocolate** will affect you and you are able to perform safely.

You may experience changes in mood or have other effects when first taking **TruChocolate**. Be sure that there is a responsible person nearby when you first take **TruChocolate** 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 **TruChocolate**. This can cause increased side effects.

ADVERSE REACTIONS

- Cardiovascular: Palpitations, tachycardia, vasodilation/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.