

PACKAGE INSERT: TOPICAL CREAM



TOPICAL CREAM

PRODUCT	PER JAR	PER DOSE	TOTAL DOSES
250MG 2OZ. JAR	2500MG THC, <5MG CBD	20MG THC, <0.01MG CBD	12.5

Product Types: Topical Cream

Cutting Ingredients: Base Cream: Organic Aloe Barbadensis (Aloe Vera) Leaf Juice, Propylene Glycol, Glycerin, Vitis Vinifera (Grape) Seed Extract, Camellia Oleifera (Japanese Green Tea) Leaf Extract, Citrus Grandis (Grapefruit) Seed Extract, Xanthan Gum, Sclerotium Gum, Camphor, Allantoin, Phenoxyethanol (and) Ethylhexylglycerin Thynus Serpillum (Thyme Serpolet) Essential Oil, Melaleuca Alternifolia (Tea Tree) Essential Oil, Lavandula Officinalis (Lavender) Essential Oil, Citric Acid

INTRODUCTION

This leaflet provides a summary of information about THC Topical Cream.

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.

THC Topical Cream contains delta-9 tetrahydrocannabinol (delta-9 THC) extracted from the Cannabis Sativa L. (marijuana) plant. delta-9 THC is a 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 sprays the medicine 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

THC Topical Cream contains clean oil extract 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," when taken orally or inhaled. However, this effect is unlikely to happen with topical use. If it does occur, the patient may experience a variety of potential effects, 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.

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

THC Topical Cream 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.

The first time that THC Topical Cream is used, the patient should put a small amount on the skin and wait at least one hour to ensure that there is no allergic reaction.

When using THC Topical Cream the patient will usually feel an effect in 15-30 minutes after application and the effect will usually last 2-6 hours, or longer. The effect may be stronger on thinner skin (such as the joints) than on thicker skin, such as the back.

Apply a small amount to the affected area and rub it gently into the skin. Repeat every 4-6 hours as needed.

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

Do not try to smoke or swallow THC Topical Cream.

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

THC Topical Cream 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.

THC Topical Cream 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.

THC Topical Cream could potentially 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 THC Topical Cream affects you and you are able to perform safely.

You may experience changes in mood or have other effects when first using THC Topical Cream. Be sure that there is a responsible person nearby when you first use THC Topical Cream 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 Topical Cream. 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.