



PACKAGE INSERT: VARINEX™ GUMMIES

VarinEx™ Gummies

PRODUCT	PER BAG	PER DOSE	TOTAL DOSES
VarinEx™	300mg	30mg	10

1 DOSE = ½ to 1 GUMMY

INGREDIENTS:

Hemp Extract (30mg per serving), Sugar, Corn Syrup, Pectin, Less Than 2% of: Sunflower Oil, Water, Flavoring, Sodium Citrate, Sodium Acid Sulfate, Citric Acid, FD&C Red No. 3, FD&C Red No. 40.

INTRODUCTION

This leaflet provides a summary of information about VarinEx™ Gummies. 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.

VarinEx™ Gummies contain hemp-derived cannabinoids (and Less than .3% D9THC). VarinEx™ gummies contain psychoactive phytocannabinoids which work on the body's internal endocannabinoid system.

IMPORTANT

CHECK WITH YOUR PHYSICIAN BEFORE STARTING A NEW DIETARY SUPPLEMENT PROGRAM. FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT.

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

If a child puts contents in his or her mouth or swallows this product take the product 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 product affects you. While taking this product, 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 product if you are pregnant or nursing.

CLINICAL PHARMACOLOGY

VarinEx™ Gummies contain mixtures of premium minor cannabinoids derived from hemp. These compounds are phytocannabinoids (plant-based cannabinoids), which mimic the effects of internally produced cannabinoids made by the brain and other parts of the human body. These compounds act on the endocannabinoid system to regulate pain and many other processes in the body. These compounds may stimulate the CB1 receptors, which are located throughout the brain and to some degree the rest of the body. When taken by mouth cannabinoids are changed in the liver to create a stronger effect.

Some cannabinoids have "psychoactive" effects on humans, sometimes called a "high." This affect varies by the person, the dose taken, and the type of method 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 the onset of action is delayed compared to inhalation. An effect is usually felt in 1-2 hours after consuming and typically lasts 4-6 hours. Effects may be felt 48 hours or more after consuming in some extreme cases.

DO NOT CONSUME MORE THAN DIRECTED BY YOUR PHYSICIAN.

In some cases use can cause psychosis, anxiety, and sedation. Lethal overdose in humans has not been reported as these compounds spare 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.

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 hemp ("cannabis naïve" patients) should be especially careful to follow this guidance.

When taking VarinEx™ Gummies the patient will usually feel an effect within 1-2 hours after ingestions and the effect will usually last 4-6 hours or longer.

Cannabinoids 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.

Starting with one half, to one full gummy, VarinEx™ Gummies should be placed inside the mouth and chewed thoroughly before swallowing.

The starting dose for VarinEx™ for most conditions is 1 gummy.

ALWAYS CONSULT WITH YOUR DOCTOR PRIOR TO USE.

SEEK CONSULTATION ON PROPER DOSAGE AND ASK IF VARINEX™ IS RIGHT FOR YOU.

CONTRAINDICATIONS

Hemp products should not be taken by patients known to be allergic.

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 D8THC+ stop using it until you have talked to your doctor.

Children should not use VarinEx™ Gummies. Cannabinoid 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.

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

Gummies can theoretically interact with other medications or grapefruit, and may increase the effect of other drugs. You should not take tinctures 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.