

**Phyto-Engineered Oils™**  
**Calming CBD/Terpene Blend**  
**DB Enterprises**

**PRODUCT DESCRIPTION**

Phyto-Engineered Oils™ (PEO) Calming CBD/Terpene Blend (manufactured and distributed by DB Enterprises) is a proprietary product made exclusively from industrial hemp oil. PEO Calming is rich in cannabidiol (CBD), other phyto-cannabinoids, terpenes and medium chain triglycerides (MCT).

PEO Calming may be useful as an adjunctive supplement to support healthy immune response and homeostasis, promote and maintain healthy mood, anti-anxiety and sleep response, possibly via the modulation of endocannabinoid system (ESC), which is known as a vital factor in the regulation of homeostasis, symptomatic relief and overall metabolic functions.

Disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

**COMMON BRAND NAMES**

PEO Calming (manufactured and distributed by DB Enterprises)

**HOW SUPPLIED**

PEO Calming is an oil tincture for oral and sublingual administration.

PEO Calming is contained in an amber glass bottle covered with a polyethylene cap. Each bottle contains 30 mL of a clear, colorless to yellow solution of industrial hemp oil with a cannabidiol content at 33 mg/mL and 8-9 mg/mL of a proprietary terpene blend. The product doesn't contain any measurable amounts of psychotropic  $\Delta^9$ -tetra-hydro-cannabinol (THC).

Non-medicinal ingredients: MCT coconut oil

**INGREDIENTS AND SUPPLEMENT FACTS**

<b>Suggested Serving Size:</b>		<b>1 mL</b>
<b>Servings Per Container:</b>		<b>Approx. 30</b>
		<b>Amount per Serving % DV</b>
Cannabidiol (CBD)		33 mg
Terpene Blend	(Linalool, Linalyl Acetate, Chamomile, Geranyl Acetate, Neryl Acetate, Lavandin, B-Caryophyllene)	8-9 mg
Medium Chain Triglycerides		1 g

% Daily Values are based on a 2,000 calorie diet

Daily Value not established

## **DOSE RECOMENDATION**

### **Dosing Considerations**

PEO Calming is for oral and/or sublingual use only. The dropper should be directed to below the tongue. It must not be applied into the nose. It is recommended to keep the administered sublingual dose in mouth (sublingual or buccal space) for 0.5 min or longer before the dose is swallowed.

The dosage of PEO Calming will depend on the nature of the desired health benefit. As an antioxidant PEO Calming may be effective at any dose. In order to have measurable wellness and beneficial physiologic effects, the daily intake should be at least around 33 mg (calculated based on CBD content) and then increased gradually according to the tolerance and achieved beneficial effects.

Dosage should be adjusted as needed and tolerated. Some individuals may require and may tolerate a higher number of doses. Individual should titrate to their optimal dosing regimen. They should be advised that it might take a few weeks to find the optimal dosing level.

### **Treatment initiation and stabilization**

- Treatment should be started at 0.1 mg/lb (~16 mg total cannabidiol, i.e. 0.5 serving, for the subject with average body weight of 150 lb) on the first day of the first week.
- On subsequent 2-3 weeks patient may gradually increase the dose as tolerated.
- If unacceptable adverse reactions such as dizziness or other type reactions develop at any time, dosing should be suspended until symptoms are relieved.
- Some individuals may be able to continue dosing at the dose reached by increasing the interval between doses; others may require their subsequent doses reduced. Individuals should then carefully re-titrate the dose to a tolerated dosage regiment.
- Re-titration of PEO Calming dose upwards or downwards may be appropriate if there are any changes in the tolerability.

### **Missed Dose**

Preferably, individual should control their daily doses of PEO Calming. In case of missed dose, individuals should follow with the next dose in their dose regiment.

### **Over dosage**

There is no recorded experience of deliberate overdose with PEO Calming.

## **CONSIDERATIONS AND PRECAUTIONS**

Despite of a good safety profile of CBD in humans, PEO Calming should not be recommended for:

- individuals with known or suspected allergy to cannabidiol or coconut oil

- individuals with significant hepatic or renal impairment
- pregnant or nursing women
- **Pediatrics**: The safety and efficacy of PEO Calming has not been established in adolescents or children under 18 years of age. Therefore, parents and caregivers need to seek their doctor's advice whether PEO Calming can be consumed by adolescents or children.
- **Geriatrics**: There are limited data available on the use of cannabidiol in elderly patients, therefore, PEO Calming should be recommended cautiously and carefully monitored in this patient population.

## STORAGE

PEO Calming should be stored upright in original container at room temperature (15°C-25°C), away from sources of heat and direct sunlight. Once opened, PEO Calming should be stored in a refrigerator (2°C-8°C).

## DRUG INTERACTIONS

PEO Calming has been consumed by adult individuals taking conventional pharmaceutical medications at the same time. No information from spontaneous reporting is available on any interactions resulting from simultaneous intake of conventional medicines with PEO Calming.

However, since the cannabidiol (CBD) is the major ingredient of PEO Calming there may be minor drug-drug interactions due to well-known CBD driven CYP450 inhibition and induction. CBD showed to be a weak inhibitor of CYP1A2, CYP2C6, CYP2D6, CYP2C19 and CYP3A4 with an EC<sub>50</sub> approximately two orders of magnitude greater than the plasma levels seen in clinical use.

In preclinical studies with P-gp, BCRP, and P-gp/BCRP knockout mice, where CBD at 10 mg/kg was injected subcutaneously, showed that CBD is not a substrate of these transporters itself.

CBD is highly bound to human plasma proteins. Although this displacement has not been confirmed *in vivo*, the dosing should be carefully monitored when administering PEO Calming to patients who are receiving other drugs which are tightly protein-bound, such as warfarin and diclofenac.

## FOOD AND HERB INTERACTIONS

No interactions with food or herbs have been established

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