Phyto-Engineered Oils™ Pain Management CBD/Terpene Blend DB Enterprises

PRODUCT DESCRIPTION

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

PEO Pain Management may be useful as an adjunctive supplement to support healthy immune response and homeostasis, promote and maintain healthy mood, reduce pain and inflammation, 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.

<u>Disclaimer</u>: "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 Pain Management (manufactured and distributed by DB Enterprises)

HOW SUPPLIED

PEO Pain Management is an oil tincture for oral and sublingual administration.

PEO Pain Management 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 50 mg/mL and 9-10 mg/mL of a proprietary terpene blend. The product doesn't contain any measurable amounts of psychotropic Δ 9-tetra-hydro-cannabinol (THC).

Non-medicinal ingredients: MCT coconut oil

INGREDIENTS AND SUPPLEMENT FACTS

Suggested Serving Size: Servings Per Container:		1 mL Approx. 30
Cannabidiol (CBD)		50 mg
Terpene Blend	(Myrcene, b-Caryophyllene, Terpinolene, s-Limonene, a-Pinene Ocimene, Humulene, Linalool)	9-10 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 Pain Management 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 Pain Management will depend on the nature of the desired health benefit. As an antioxidant PEO Pain Management may be effective at any dose. In order to have measurable wellness and beneficial physiologic effects, the daily intake should be at least around 50 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 (~25 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 Pain Management 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 Pain Management. 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 Pain Management.

CONSIDERATIONS AND PRECAUTIONS

Despite of a good safety profile of CBD in humans, PEO Pain Management 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
- <u>Pediatrics</u>: The safety and efficacy of PEO Pain Management 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 Pain Management can be consumed by adolescents or children.
- <u>Geriatrics</u>: There are limited data available on the use of cannabidiol in elderly patients, therefore, PEO Pain Management should be recommended cautiously and carefully monitored in this patient population.

STORAGE

PEO Pain Management 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 Pain Management should be stored in a refrigerator (2°C-8°C).

DRUG INTERACTIONS

PEO Pain Management 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 Pain Management.

However, since the cannabidiol (CBD) is the major ingredient of PEO Pain Management 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 EC50 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 Pain Management 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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