CANNAVERA PAIN RELIEF- capsaicin oil Leading Edge Pharms, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CANNAVERA PAIN RELIEF OIL

DRUG FACTS

Active Ingredients

Capsaicin, 0.10%

Purpose

External Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints due to:

• simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only.

Read all warnings and directions before use.

Test first on small area of skin.

IF PREGNANT OR BREASTFEEDING

- Ask a health professional before use.
- CA AB-45: the FDA strongly advises against the use of cannabis, including CBD, in any form, during pregnancy or while breastfeeding.

Do not use.

• If you are allergic to any ingredients of this product

When using this product

- You may experience a burning sensation that generally disappears after several days of regular use. The intensity of this reaction varies among individuals and may be severe.
- Avoid contact with the eyes or mucous membranes. Do not bandage tightly or use with a heating pad.

Stop use and ask a doctor if

• Condition worsens or does not improve after regular use. • Severe burning persists or blistering occurs.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Adults and children 18 years of age or older

• Apply a thin film of oil to affected area and gently rub in until fully absorbed • Wash hands with soap and water after use • Apply to affected area not more than 3 to 4 times daily.

Children under 18 yearsask a doctor

Other information

• Store at 15° - 30°C (59° - 86°F)

Inactive Ingredients

Capric Triglycerides, Grape Seed Oil, Rosehip Oil, Passion Fruit Seed Oil, Eucalyptus Leaf Oil, Propanediol, Ethanol SDA 3A, Hemp (Cannabis sativa L.) Leaf Extract, hosphatidylcholine, Aloe Barbadensis Leaf Powder, Sage Leaf Extract, Arnica Leaf Extract, Rosemary Leaf Extract, Bergamot Fruit Oil, Sweet Almond Oil, Tocopherol Acetate, C12-15 Alkyl Benzoate, Lavender Oil, Chamomile Flower Extract, Capryl Glycol, Hexylene Glycol, Phenoxyethanol, Ethylhexylglycerin, Ascorbyl Palmitate, Ascorbic Acid Tocopherol Acetate, Citric Acid.

Questions?

Call 1-888-536-2872

Package Labeling:



CANNAVERA OTC TOPICAL PAIN RELIEF IS A STEP-WISE APPROACH TO PAIN MANAGEMENT



CANNAVERA Pain Relief Oil is a proprietary blend made with natural oils and botanical extracts designed to provide FAST, SAFE and EFFECTIVE relief from arthritis, back, neck and shoulder pain.

The hemp leaf extract used in this formulation is from the Cannabis sativa *L*. plant cultivated and processed in strict accordance with local, state and federal laws.

CANNAVERA products are FDA registered OTC topical medications produced in cGMP audited manufacturing facilities to ensure the highest quality control standards.

- NO ARTIFICIAL DYES
- NO SYNTHETIC FRAGRANCES
- NO STEROIDS
- NO PARABENS
- NO PETROLATUM
- NOT TESTED ON ANIMALS



THC FREE: Non-detectable below the lowest level that can be consistently detected using valid scientific analytical tools.



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- IF PREGNANT OR BREASTFEEDING
- Ask a health professional before use.
 CAAB-45: the FDA strongly advises against the use of cannabis, including CBD, in any form, during pregnancy or while breastfeeding.

Do not use.

 On wounds or damaged skin
 If you are allergic to any ingredients of this product

When using this product

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 Avoid contact with the eyes or mucous membranes.
 Do not bandage tightly or use with a heating pad.

Stop use and ask a doctor if

 Condition worsens or does not improve after regular use.
 Severe burning persists or blistering occurs.

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DRUG FACTS CONTINUED

Inactive Ingredients

Capric Triglycerides, Grape Seed Oil,
Rosehip Oil, Passion Fruit Seed Oil,
Eucalyhtus Led Oil, Propanediol, Ethanol
SDA 3A, Hemp (Cannabis sativa L.) Leaf
Estract, hosphatiglycholine, Aloe Barbadensis
Leaf Powder, Sage Leaf Extract, Amica Leaf
Extract, Rosemary Leaf Extract, Bergamot
Fruit Oil, Sweet Aimond Oil, Tocopherol
Acetale, C12-15-Alkyl Benzoate, Lavender
Oil, Chamoniel Flower Extract, Capryl Glycol,
Hexylene Glycol, Phenoxyethanol,
Ethylmexylglycerin, Ascorbyl Palmitate,
Ascorbic Acid Tocopherol Acetale, Citric Acid.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Questions? Call 1-888-536-2872

NDC: 80295-100-01





Distributed by LENCURA, www.lencura.com a division of Leading Edge Pharms, Inc., Henderson, NV 89012 (USA)

CANNAVERA PAIN RELIEF

capsaicin oil

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80295-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	1 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
TRICAPRIN (UNII: O1PB8EU98M)		
GRAPE SEED OIL (UNII: 930MLC8XGG)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		
PROPANEDIOL (UNII: 5965N8W85T)		
CANNABIS SATIVA WHOLE (UNII: B5ONF538PB)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
SAGE (UNII: 065C5D077J)		
ROSEMARY (UNII: IJ67X351P9)		
ALMOND OIL (UNII: 66YXD4DKO9)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
LAVENDER OIL (UNII: ZBP1YXW0H8)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
HEXYLENE GLYCOL (UNII: KEH0A3F75J)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
ASCORBIC ACID (UNII: PQ6CK8PD0R)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80295-100- 01	1 in 1 BOX	08/01/2023			
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	08/01/2023			

Labeler - Leading Edge Pharms, Inc. (071092942)

Revised: 8/2023 Leading Edge Pharms, Inc.