

OP6 MENTHOL WARMING PAIN CREAM- menthol cream
Renu Laboratories, 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.

op6 Menthol Warming Pain Cream

Menthol 5 percent

Warnings

For external use only

When using this product do not bandage tightly

avoid contact with eye

do not apply to wounds or damaged skin

Stop use and ask doctor

if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

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

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

Topical Analgesic

Directions

adults and children 12 years of age and older

apply generously to affected area

massage into painful area until thoroughly absorbed into skin

repeat as necessary

Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cannabis Sativa (Hempseed) Oil and Hemp Derived Cannabidiol (CBD) Extract and proprietary terpene blend (Myrcene, b-Caryophyllene, d-Limonene, Humulene, Terpinolene, a-Pinene, Linalool, b-Pinene, Valencene, Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, Deionized Water, Emulsifying Wax, Glyceryl Stearate, Grapefruit Oil, Hamamelis Virginiana (Witch Hazel), Laureth-7, Magnesium Chloride, Magnesium Sulfate, Mangifera Indica (Mango) Seed Butter, Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive) Oil, Olus (Vegetable) Oil, PEG-100, Phenoxyethanol, Polyacrylamide, Stearic Acid

Uses

for temporary relief of minor aches and pains associated with
arthritis
simple backache
muscle strains
sprains
bruises

QUESTIONS OR COMMENTS

631 697 0296

ACD HEALTH AND WELLNESS LLC

ACDHEALTH.COM

PRODUCT LABEL AND BOX ART



TOP

1.25 inches

**Broad Spectrum Hemp
CBD Oil 1200 mg**

Serious Pain Relief for Serious Athletes

Manufactured for:
ACD Health & Wellness, LLC
Cold Spring Harbor, NY 11724

**1200mg
CBD Oil**



CBD SPORT



ACDHealth.com

Menthol Warming Pain Cream

Net Wt. 4 oz.

7 inches

Topical Analgesic

INSIDE TOP

Drug Facts

Active Ingredients:

Menthol 5%Topical Analgesic

Uses: for temporary relief of minor aches and pains associated with • arthritis • simple backache • muscle strains • sprains • bruises

Warnings: For external use only

When using this product: Do not bandage tightly •

Drug Facts (continued)

avoid contact with eyes • do not apply to damaged skin • do not use heating pads or heating devices.

Stop use and ask a doctor if: condition worsens or if symptoms persist for more than 7 days and occur again within a few days.

Keep out of reach of children if swallowed, get help or contact a poison control center.

BASE

Directions: adults and children 12 years of age and older • apply generously to affected area • massage into painful area until thoroughly absorbed into skin • repeat as necessary.

Inactive Ingredients: Butyrospermum Parkii, (Shea) Butter, C13-14 Isoparaffin, Cannabis Sativa (Hemp) Seed Oil (Full Spectrum) and Hemp Derived Cannabidiol (CBD) Extract and proprietary terpene blend (Myrcene, b Caryophyllene, d-Limonene, Humulene, Terpinolene, a-Pinene, Linalool, b-Pinene, Valencene) Capsicum Frutescens Fruit Extract, Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, Deionized Water, Emulsifying Wax, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel), Laureth-7, Magnesium Chloride, Magnesium Sulfate, Mangifera Indica (Mango) Seed Butter, Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive Oil), Olus (Vegetable Oil), PEG-100 Stearate, Phenoxyethanol Polyacrylamide, Stearic Acid

**Questions or
631-697-02**

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OP6 MENTHOL WARMING PAIN CREAM

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-681
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.6 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
TABASCO PEPPER (UNII: J1M3NA843L)	
.BETA.-PINENE (UNII: 4MS8VHZ1HJ)	
HUMULENE (UNII: 54W56MD2WD)	
TERPINOLENE (UNII: N9830X5KSL)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
VALENCENE (UNII: 96H21P91IG)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)	
CORN OIL (UNII: 8470G57WFM)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
COCONUT OIL (UNII: Q9L0O73W7L)	
WHITE WAX (UNII: 7G1J5DA97F)	
SHEA BUTTER (UNII: K49155WL9Y)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
LAURETH-7 (UNII: Z95S6G8201)	
WITCH HAZEL (UNII: 101I4J0U34)	
MYRCENE (UNII: 3M39CZS25B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
CARYOPHYLLENE (UNII: BHW853AU9H)	
.ALPHA.-PINENE (UNII: JPF3YI7O34)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-681-01	1 in 1 BOX	09/14/2021	
1	NDC:76348-681-04	112 g in 1 JAR; 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	09/14/2021	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-681)

Revised: 9/2021

Renu Laboratories, Inc.