

OP6 MENTHOL COOLING 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 Cooling 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

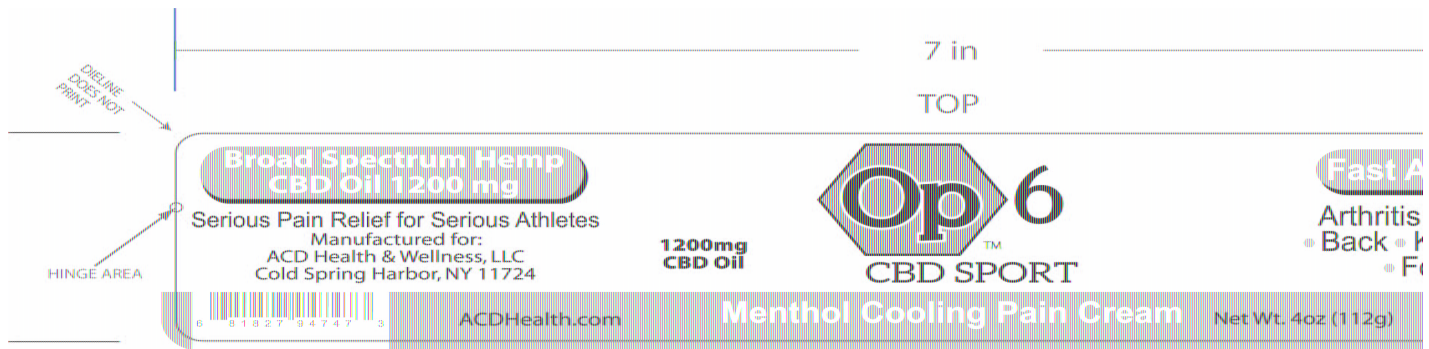
631 697 0296

ACD HEALTH AND WELLNESS LLC

ACDHEALTH.COM

PRODUCT LABEL AND BOX ART





INSIDE
THIS SIDE WILL BE
MIRRORED ON PLATES

Drug Facts		Drug Facts (continued)
Active Ingredients: Menthol 5%	Purpose Topical Analgesic	avoid contact with eyes • do not apply to w damaged skin • do not use heating pads or heating devices.
Uses: for temporary relief of minor aches and pains associated with • arthritis • simple backache • muscle strains • sprains • bruises		Stop use and ask a doctor if: condition wo if symptoms persist for more than 7 days or and occur again within a few days
Warnings: For external use only		Keep out of reach of children if swallowed, help or contact a poison control center rig
When using this product: Do not bandage tightly •		

PEEL TAB

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.	Questions or Comme 631-697-0296
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), 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	Manufacturer ACD Health & Wel Cold Spring Harbor ACDHealth.c

HINGE AREA

DEADENER & RELEASE



OP6 MENTHOL COOLING PAIN CREAM

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-680
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
.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:76348-680-01	1 in 1 BOX	09/10/2021	
1	NDC:76348-680-04	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	09/10/2021	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-680)

Revised: 9/2021

Renu Laboratories, Inc.