# OP 6 MENTHOL COOLING ROLL ON- menthol liquid 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.

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#### **OP 6 MENTHOL COOLING ROLL ON**

#### Active ingredient

Menthol 5 percent

#### **Purpose**

Topical Analgesic

#### Uses

for temporary relief of minor aches and pains of muscles and joints associated with

- bruises
- sprains
- arthritis
- strains

#### Warnings

#### For external use only

#### When using this product

Do not bandage tightly

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

#### Stop use and ask a 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 a Poison Control Center right away.

#### **Directions**

- adults and children 12 years of age and older, apply to affected area no more than 10 times a day as needed for pain.
- children under 12 years of age: do not use, consulta a doctor.

Arnica Montana (Arnica) Flower Extract, Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol Extract with proprietary terpene blend (Limonene, Myrcene, Caryophyllene, Linalool, Pinene, Terpineol), Deionized Water, Fragrance, Hamamelis Virginiana (Witch Hazel), Hydroxyethyl Cellulose, Isopropyl Alcohol, Magnesium Chloride, Mentha piperita (Peppermint) Leaf Oil, Polysorbate 80, Potassium Sorbate, Sodium

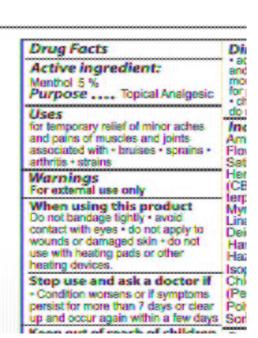
Benzoate.

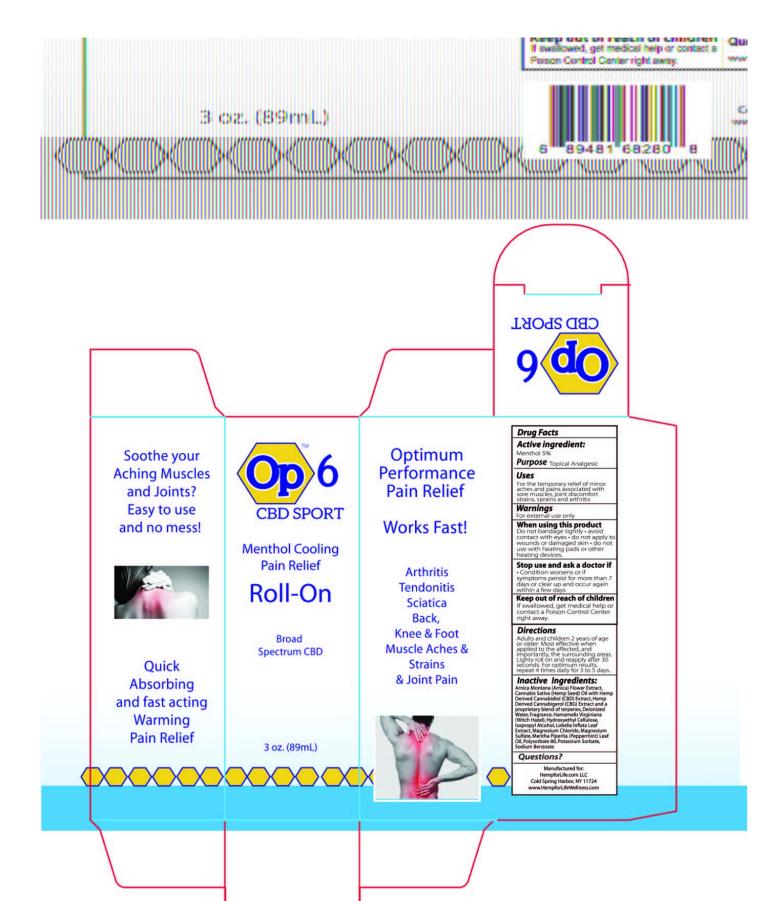
#### **Questions? Comments?**

www.HempforLifeWellness.com
PRODUCT LABEL AND PRODUCT BOX

 $4.625 \times 3.187$ 







### **OP 6 MENTHOL COOLING ROLL ON**

menthol liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76348-670

**Route of Administration** TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 4.2 g in 84 g

Inactive Ingredients	
Ingredient Name	Strength
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLCELLULOSE (4000 CPS) (UNII: MRJ667KA5E)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
WITCH HAZEL (UNII: 101I4J0U34)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
PINENE (UNII: 996299PUKB)	
ARNICA MONTANA (UNII: O80TY208ZW)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
MYRCENE (UNII: 3M39CZS25B)	
CARYOPHYLLENE (UNII: BHW853AU9H)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76348- 670-01	1 in 1 BOX	08/02/2021			
1	NDC:76348- 670-03 84 g in 1 APPLICATOR; Type 0: Not a Combination Product					

Marketing Information			
Marketing	Application Number or Monograph Citation	Marketing Start	Marketing End
Category		Date	Date

OTC monograph not final	part348	08/02/2021	

# Labeler - RENU LABORATORIES, INC. (945739449)

# **Registrant -** RENU LABORATORIES, INC. (945739449)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
RENU LABORATORIES, INC.		945739449	manufacture(76348-670)	

Revised: 8/2021 RENU LABORATORIES, INC.