

OP 6 MENTHOL WARMING 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.

OP 6 MENTHOL WARMING 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, consult 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, Terpeneol), 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

OP6 WARMING ROLL ON LABEL AND OUTER BOX

Size: (W) 1.75" (H) 5.25" (D) 1.75"



Soothe your Aching Muscles and Joints? Easy to use and no mess!



Quick Absorbing and fast acting Warming Pain Relief



Menthol Warming Pain Relief

Roll-On

Broad Spectrum CBD

3 oz. (89mL)

Optimum Performance Pain Relief

Works Fast!

Arthritis Tendonitis Sciatica Back, Knee & Foot Muscle Aches & Strains & Joint Pain



Drug Facts
Active ingredient: Menthol 5%
Purpose Topical Analgesic
Uses For the temporary relief of minor aches and pains associated with sore muscles, joint discomfort, strains, sprains and arthritis
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 2 years of age or older: Most effective when applied to the affected, and importantly, the surrounding areas. Lightly roll on and reapply after 30 seconds. For optimum results, repeat 4 times daily for 3 to 5 days.
Inactive Ingredients: Arnica Montana (Arnica) Flower Extract, Cannabis Sativa (Hemp Seed) Oil with Hemp Derived Cannabidiol (CBD) Extract, Hemp Derived Cannabigerol (CBG) Extract and a proprietary blend of terpenes, Capsicum Frutescens (Pepper) Extract, Deionized Water, Fragrance, Hamamelis Virginiana (Witch Hazel), Hippophae Rhamnoides (Sea Berry) Fruit and Seed Oil, Hydroxyethyl Cellulose, Isopropyl Alcohol, Lobelia Inflata Leaf Extract, Magnesium Chloride, Magnesium Sulfate, Mentha Piperita (Peppermint) Leaf Oil, Polysorbate 80, Potassium Sorbate, Sodium Benzoate
Questions? Manufactured for: HempforLife.com LLC Cold Spring Harbor, NY 11724 www.HempforLifeWellness.com

4.625 x 3.187



OP 6 MENTHOL WARMING ROLL ON			
menthol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-660
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	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)
TABASCO PEPPER (UNII: J1M3NA843L)
MYRCENE (UNII: 3M39CZS25B)
CARYOPHYLLENE (UNII: BHW853AU9H)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-660-01	1 in 1 BOX	08/02/2021	
1	NDC:76348-660-03	84 g in 1 APPLICATOR; 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	08/02/2021	

Labeler - RENU LABORATORIES, INC. (945739449)

Registrant - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-660)

Revised: 8/2021

RENU LABORATORIES, INC.