

**SOLID ROOTS ROLL-ON RELIEF- menthol 3 percent 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.

Solid Roots AUTHENTIC BLENDS Roll-On Relief

Menthol 3 percent

Topical Anesthetic

Uses

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

- bruises
- sprains
- arthritis
- strains

For external use only

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

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

Adults and children twelve years of age and older,

apply to affected area no more than ten times a day as needed for pain

children under twelve years of age do not use, consult a doctor

Arnica Montana (Arnica) Flower Extract, Cannabis Sativa (Hemp) Seed Oil and Hemp Derived Cannabidiol (CBD) Extract, Deionized Water, Citrus Paradisi (Grapefruit) Extract, Hippophae Rhamnoides (Sea Berry) Fruit Oil, Hippophae Rhamnoides (Sea Berry) Seed Oil, Hydroxyethyl Cellulose, Isopropyl Alcohol, Lobelia Flower Extract, Magnesium Chloride, Magnesium Gluconate, Magnesium Myristate, Magnesium Orotate, Magnesium Sulfate, Menth Piperita (Peppermint) Leaf Oil, Polysorbate 80, Potassium Sorbate, Sodium Benzoate, Hamamelis Virginiana (Witch Hazel)

Questions? Comments ?

HELLO@AUTHENTICBLENDS.COM

AUTHENTIC BLENDS, LLC

PRODUCT MULTI-LAYER LABEL

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DRUG FACTS		STOP USING AND ASK A DOCTOR IF: Conditions worsen or if symptoms persist for more than 7 days or clear up and occur again within a few days. KEEP OUT OF REACH FROM CHILDREN: If swallowed, get medical help or contact a poison control center right away. QUESTIONS? COMMENTS? HELLO@AUTHENTICBLENDS.COM	AUTHENTIC BLENDS, LLC HAVERTOWN, PA 19083
ACTIVE INGREDIENTS Menthol 3%	PURPOSE Topical Anesthetic		
USE for temporary relief of minor aches and pains of muscles and joints associated with bruises, sprains, strains, & arthritis WARNINGS FOR EXTERNAL USE ONLY			
WHEN USING THIS PRODUCT do not bandage tightly • Avoid contact with the eyes • Do not apply to wounds or damaged skin. Do not use with heating pads or other heating devices.			



<p>DIRECTIONS: Adults and children 12 years of age and older apply to the 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.</p>	<p>Inactive Ingredients: <i>Arnica Montana</i> (Arnica) Flower Extract, <i>Cannabis Sativa</i> (Hemp) Seed Oil and Hemp-Derived Cannabidiol (CBD) Extract, Deionized Water, <i>Citrus Paradisi</i> (Grapefruit) Extract, <i>Hippophae Rhamnoides</i> (Sea Berry) Fruit Oil, <i>Hippophae Rhamnoides</i> (Sea Berry) Seed Oil, Hydroxyethyl Cellulose Isopropyl Alcohol, <i>Lobelia</i> Flower Extract, Magnesium Chloride, Magnesium Gluconate, Magnesium Myristate, Magnesium Orotate, Magnesium Sulfate, <i>Mentha Piperita</i> (Peppermint) Leaf Oil, Polysorbate 80 Potassium Sorbate, Sodium Benzoate, <i>Virginia Hamamelis</i> (Witch Hazel).</p>
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LABEL IS A MULTI-LAYER. PAGE 1, PAGE 2 AND PAGE 3 ALL PART OF THE PEEL BACK LABEL

SOLID ROOTS ROLL-ON RELIEF

menthol 3 percent liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-481
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	0.84 g in 28 g
Inactive Ingredients			

Ingredient Name	Strength
GRAPEFRUIT (UNII: O82C39RR8C)	
WATER (UNII: 059QF0KO0R)	
METHYLCELLULOSE (4000 CPS) (UNII: MRJ667KA5E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
MAGNESIUM OROTATE (UNII: GI96W46M5A)	
LOBELIA INFLATA LEAF (UNII: 7QFT17RLRG)	
MAGNESIUM GLUCONATE (UNII: T42NAD2KHC)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
ARNICA MONTANA (UNII: O80TY208ZW)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
WITCH HAZEL (UNII: 101I4J0U34)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-481-01	28 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	06/13/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/13/2022	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-481)

Revised: 6/2022

RENU LABORATORIES, INC.