

SUGARLOAF ORGANICS MENTHOL REVIVE- 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.

SUGARLOAF MENTHOL REVIVE MENTHOL PAIN CREAM

Menthol 5%

Topical Analgesic

For temporary relief of minor aches and pains associated with

- arthritis
- simple backache
- muscle strains
- sprains
- bruises

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

Keep out of reach of children.

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

Instructions: Massage into skin until thoroughly absorbed. Repeat as needed. Store at room temperature.

Butyrospermum Parkii (Shea) Butter, Cannabis Sativa (Hemp) Seed Oil, with a proprietary blend of terpenes (alpha-bisabolol,

alpha-humulene, beta-caryophyllene, caryophyllene oxide, gualol, linalool),

Cetearyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, C13-14 Isoparaffin, Deionized Water, Emulsifying Wax, Ethylhexylglycerin, Fragrance, Hemp-derived Cannabichromene (CBC), Cannabidiol (CBD), and Cannabigerol (CBG),

Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel), Laureth-7, Magnesium Sulfate, Mangifera Indica (Mango) Seed Buter,

Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive) Oil, Olus Oil (Vegetable), PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Stearic Acid

Sugarloaf Organics

Drums, PA 18222

P: 570.866.5882

www.sugarloafororganic.com

Sugarloaf Organics Revive Menthol Pain Cream

Label and Box

Account Name: Sugarloaf Organic
 Opportunity Name: 4oz CBD Jar
 Filename: 12114_D
 L x W x D: 2¹¹/₁₆ x 2¹¹/₁₆ x 2¹⁵/₁₆
 Blank Size: 11¹¹/₃₂ x 10
 Board: .016 SBS
 Date: 12-Aug-2020
 Print Side Up





INSIDE TOP

<p>Drug Facts Active Ingredients: Menthol 5% Purpose 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</p>	<p>Drug Facts (continued) avoid contact with eyes • do not apply to wounds or damaged skin • do not use 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</p>
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BASE

<p>Instructions: Massage into skin until thoroughly absorbed. Repeat as needed. Store at room temperature.</p> <p>Inactive Ingredients: Butyrospermum Parkii (Shea) Butter, CannaBle Stativa (Hemp) Seed Oil with a proprietary blend of terpenes (alpha-bisabolol, alpha-humulene, beta-caryophyllene, caryophyllene oxide, gualul, linalool), Cocosyl Alcohol, Cetearyl Glucoside, Cocos Nucifera (Coconut) Oil, C13-14 Isoparaffin, Emulsifying Wax, Ethylhexylglycerin, Fragrance, Hexamethyldisiloxane (Cap), Cannabidiol (CBD), and Cannabigerol (CBG), Dipentyl Stearate, Hamamelis virginiana (Witch Hazel), Laureth-7, Magnesium Sulfate, Mangifera indica (Mango) Seed Butter, Nettle (Plantain) Crispener Oil, Olive Squalene (Olive) Fruit Oil, Oley (Vegetable) Oil, PEG-100 Stearate, Phenoxyethanol, Polyacrylamide, Stearic Acid.</p>	 <p>Grown and Distributed by: Sugarloaf Organics Drums, PA 18222 P: 570.866.5882 www.sugarloaforganic.com</p>
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SUGARLOAF ORGANICS MENTHOL REVIVE

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-996
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.9 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
CANNABIGEROL (UNII: J1K406072N)	
CANNABICHROMENE (UNII: K4497H250W)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
OLIVE OIL (UNII: 6UYK2WLWLE)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WITCH HAZEL (UNII: 101I4J0U34)	
SHEA BUTTER (UNII: K49155WL9Y)	
LAURETH-7 (UNII: Z95S6G8201)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
WHITE WAX (UNII: 7G1J5DA97F)	

STEARIC ACID (UNII: 4ELV7Z65AP)
COCONUT OIL (UNII: Q9L0O73W7L)
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)
CORN OIL (UNII: 8470G57WFM)
CANNABIDIOL (UNII: 19GBJ60SN5)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-996-01	1 in 1 BOX	04/25/2023	
1	NDC:76348-996-04	118 mL 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	04/25/2023	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-996)

Revised: 4/2023

RENU LABORATORIES, INC.