ELEVATE COOLING THERAPY TWIST UP- 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.

elevate COOLING THERAPY TWIST UP

Menthol

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 a Poison Control Center right away.

Purpose

Topical Analgesic

Questions? Call 215.660.9123 or email us at info@elevatecbd.com

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.

Other information

Keep out of direct sunlight

elevate CBD COOLING THERAPY TWIST UP TOPICAL with Menthol

Uses

• For external use on muscles and joints where you feel soreness

Massage desired amount into affected skin area no more than 10 times daily or as directed by your doctor.

children under 12 years of age consult your physician.

Warnings

- For external use only
- When using this product do not bandage tightly
- avoid contact with eyes
- do not apply to to wounds or damaged skin
- do not use with heating pads or other heating devices

Inactive Ingredients

Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cannabis Sativa (Hempseed) Oil and Hemp Derived Cannabidiol (CBD) Extract, 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, Mint Oil, Olea Europaea (Olive) Oil, Olus (Vegetable) Oil, PEG-100, Phenoxyethanol, Polyacrylamide, Stearic Acid

elevate Twist Up Topical label



9/09/2019 Elevate 2oz Cream Stick Cooling Therapy 5.685 x 2.5



ELEVATE COOLING THERAPY TWIST UP

menthol cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76348-456

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.8 g in 56 g

Inactive Ingredients	
Ingredient Name	Strength
PEPPERMINT OIL (UNII: AV092KU4JH)	
WITCH HAZEL (UNII: 10114J0U34)	
SHEA BUTTER (UNII: K49155WL9Y)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
CANNABIDIOL (UNII: 19GBJ60SN5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

OLIVE OIL (UNII: 6UYK2W1W1E)	
COCONUT OIL (UNII: Q9L0O73W7L)	
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WHITE WAX (UNII: 7G1J5DA97F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
CORN OIL (UNII: 8470G57WFM)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348- 456-01	56 g in 1 APPLICATOR; Type 0: Not a Combination Product	10/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2019	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment				
Name	Address	ID/FEI	Business Operations	
Renu Laboratories, Inc.		945739449	manufacture(76348-456)	

Revised: 1/2022 Renu Laboratories, Inc.