

ELEVATE HEATING THERAPY TWIST UP- menthol cream 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 HEATING THERAPY TWIST UP

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Uses

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

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 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

- 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.

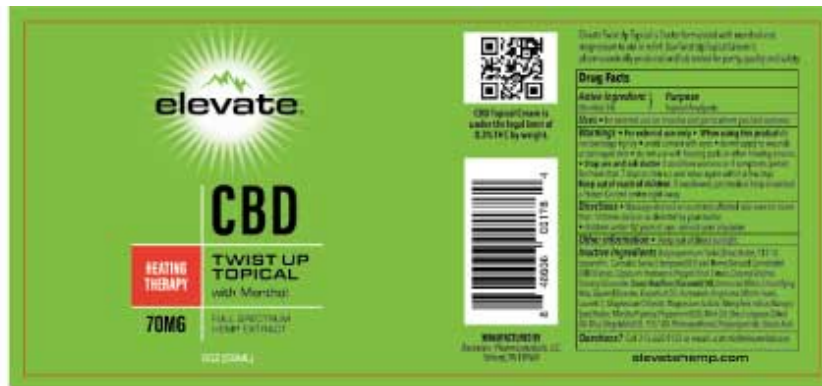
Other information

- Keep out of direct sunlight.

Inactive Ingredients Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cannabis Sativa (Hempseed) Oil and Hemp Derived Cannabidiol (CBD) Extract, Capsicum Frutescens (Pepper) Fruit 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

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

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



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



PMS179C

Base colors



PMS 376C



BLACK

Elevate 2oz Cream Stick

ELEVATE HEATING THERAPY TWIST UP

menthol cream cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76348-454 |
| 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 |
|--|----------|
| CANNABIDIOL (UNII: 19GBJ60SN5) | |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S) | |
| CETEARYL GLUCOSIDE (UNII: 09FUA47KNA) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| LAURETH-7 (UNII: Z95S6G8201) | |

| |
|---|
| WITCH HAZEL (UNII: 101I4J0U34) |
| POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I) |
| MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2) |
| OLIVE OIL (UNII: 6UYK2W1W1E) |
| CORN OIL (UNII: 8470G57WFM) |
| COCONUT OIL (UNII: Q9L0O73W7L) |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) |
| PEG-100 STEARATE (UNII: YD01N1999R) |
| PEPPERMINT OIL (UNII: AV092KU4JH) |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |
| WATER (UNII: 059QF0KO0R) |
| SHEA BUTTER (UNII: K49155WL9Y) |
| TABASCO PEPPER (UNII: J1M3NA843L) |
| WHITE WAX (UNII: 7G1J5DA97F) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76348-454-01 | 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(76348-454) |

Revised: 1/2022

RENU LABORATORIES, INC.