

**MINTED LEAF COLD THERAPY RELIEF WITH CBD AND MENTHOL ROLL ON-menthol cream**

**MMG Consumer Brands, LLC**

*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.*

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**MINTED LEAF Cold Therapy Relief with CBD and Menthol Roll-On**

***Drug Facts***

**Active ingredient**

Menthol 4.00%

**Purpose**

Topical Analgesic

***Indications***

- For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis
- simple backache
- sprains
- bruises and strains.

***Warnings:***

- For external use only.
- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult physician.

**Keep out of reach of children.**

If swallowed, consult physician.

**Do not apply**

to wounds or damaged skin.

- Do not bandage tightly.

**If pregnant or breast feeding,**

contact physician prior to use.

***Directions***

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

**Additional Information**

- Store at room temperature.

**Other Ingredients:**

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arctium Lappa (Burdock) Root Extract, Arnica Montana Flower Extract, Boswellia Serrata Extract, Camellia Sinensis (Green Tea) Extract, Broad Spectrum Hemp Oil, Cetearyl Oliviate, Cetyl Alcohol, Citric Acid, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Ilex Paraguariensis (Yerba Mate') Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Extract, Methylsulfonylmethane (MSM), Phenoxyethanol, Sorbitan Oliviate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Xanthan Gum.

**Package Labeling:**

**MINTED LEAF COLD THERAPY RELIEF WITH CBD AND MENTHOL ROLL ON**

menthol cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:73102-065 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  |  | Basis of Strength   | Strength             |                    |
|--|--|---|----------------------|--------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) |  | MENTHOL   | 40 mg in 1 mL        |                    |
| <b>Inactive Ingredients</b>                            |  |   |                      |                    |
| Ingredient Name  |  | Strength  |                      |                    |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                      |  |   |                      |                    |
| WATER (UNII: 059QF0KO0R)                               |  |   |                      |                    |
| ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)                   |  |   |                      |                    |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)               |  |   |                      |                    |
| INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)                 |  |   |                      |                    |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)                      |  |   |                      |                    |
| CANNABIS SATIVA WHOLE (UNII: B5ONF538PB)               |  |   |                      |                    |
| CETEARYL OLIVATE (UNII: 58B69Q84JO)                    |  |   |                      |                    |
| CETYL ALCOHOL (UNII: 936JST6JCN)                       |  |   |                      |                    |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)             |  |   |                      |                    |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                  |  |   |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                            |  |   |                      |                    |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)               |  |   |                      |                    |
| SUNFLOWER OIL (UNII: 3W1JG795YI)                       |  |   |                      |                    |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)            |  |   |                      |                    |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)                   |  |   |                      |                    |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)                 |  |   |                      |                    |
| MELISSA OFFICINALIS (UNII: YF70189L0N)                 |  |   |                      |                    |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)                    |  |   |                      |                    |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                      |  |   |                      |                    |
| SORBITAN OLIVATE (UNII: MDL271E3GR)                    |  |   |                      |                    |
| STEARIC ACID (UNII: 4ELV7Z65AP)                        |  |   |                      |                    |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)          |  |   |                      |                    |
| XANTHAN GUM (UNII: TTV12P4NEE)                         |  |   |                      |                    |
| <b>Packaging</b>                                       |  |   |                      |                    |
| #  | Item Code                                | Package Description   | Marketing Start Date | Marketing End Date |
| 1  | NDC:73102-065-00                         | 89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 08/01/2019           |                    |
| <b>Marketing Information</b>                           |  |   |                      |                    |
| Marketing Category                                     | Application Number or Monograph Citation | Marketing Start Date  | Marketing End Date   |                    |
| OTC monograph not final                                | part348                                  | 08/01/2019  |                      |                    |

**Labeler** - MMG Consumer Brands, LLC (117036455)