PAIN RELIEF ROLL-ON- menthol liquid Sagely Enterprises 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.

Pain Relief Roll-On

Active ingredient

Menthol 10%

Purpose

Menthol 10%.....Topical analgesic

Uses

temporarily relieves the minor aches and pains of muscles and joints associated with:

- arthritis
- sprains
- muscle strains
- bruises

Warnings

For external use only.

Do not use

- on wounds, or damaged, broken, or irritated skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

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 pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Use only as directed

Adults and children over 12 years:

- apply a thin layer to affected area
- massage into painful area
- repeat as necessary, but no more than 3 to 4 times daily
- Children 12 years or younger: ask a doctor.

Inactive ingredients

Water, Propanediol, Capryloyl Glycerin/Sebacic Acid Copolymer, Coco-Caprylate, Glyceryl Stearate, Glyceryl Stearate Citrate, Diheptyl Succinate, Glycerin, Lauryl Glucoside, Polyglyceryl-2 Dipolyhydroxystearate, Microcrystalline Cellulose, Cellulose Gum, Phytic Acid, Leuconostoc/Radish Root Ferment Filtrate, Boswellia Serrata Resin Extract, Polyglyceryl-6 Caprylate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Cocoate, Polyglyceryl-6 Ricinoleate, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-6 Caprylate/Caprate, Camphor, Arnica Montana Flower Extract, Aloe Barbadensis Leaf Extract, Xanthan Gum, Lavender (Lavandula Hybrida) Oil, Peppermint (Mentha Piperita) Oil, Caprylyl Glyceryl Ether, Caprylhydroxamic Acid

Sagely Naturals
Pain Relief Roll-On
Instant Cooling
With 10% Menthol
95% Natural Ingredients

2 FL OZ / 60 ML



PAIN RELIEF ROLL-ON

This roll-on makes for an easy application, even in hard-to-reach spots. The lightweight formula dissolves quickly and leaves skin feeling smooth, never greasy.

Massage onto sore areas daily or as needed.

UPPER BACK AND SHOULDERS KNEES BACK OF NECK

ABOUT SAGELY NATURALS

LOWER BACK

Kaley and Kerrigan launched Sagety
Naturals in 2015 with a specific goal
in mind: to unearth clean and powerful
healing alternatives. Through thoughtful
crafting and sourcing, we developed a
collection of soothing products that deliver
temporary relief from minor aches, pains,
and tensions caused by day-to-day life —
offering a trusted, welcome approach to
whole-body healing.



PAIN RELIEF ROLL-ON



INSTANT COOLING

Keep this carton for important Drug Facts information

Drug Facts

Active ingredient Purpose Menthol 10%.....Topical analgesic

Uses temporarily relieves the minor aches and pains of muscles and joints associated with: ■ arthritis ■ sprains ■ muscle strains ■ bruises

Warnings For external use only.

Do not use

- on wounds, or damaged, broken, or irritated skin with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

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 pregnant or breastfeeding, ask a health professional before use

Keep out of reach of children.

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

195% of our ingredients can be found in nature

Drug Facts (continued)

Directions ■ Use only as directed Adults and children over 12 years:

- apply a thin layer to affected area
- massage into painful area
- repeat as necessary, but no more than 3 to 4 times daily
- Children 12 years or younger: ask

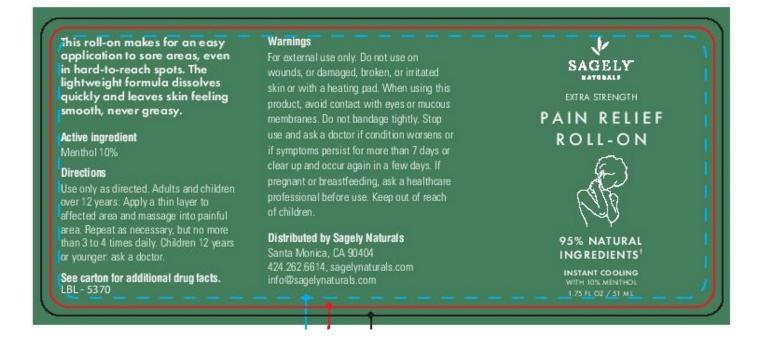
Inactive ingredients

Water, Propanediol, Capryloyl Glycerin/ Sebacic Acid Copolymer, Coco-Caprylate, Glyceryl Stearate, Glyceryl Stearate Citrate, Diheptyl Succinate, Glycerin, Lauryl Glucoside, Polyglyceryl-2 Dipolyhydroxys-tearate, Microcrystalline Cellulose, Cellulose Gum, Phytic Acid, Leuconostoc/ Radish Root Ferment Filtrate, Boswellia Serrata Resin Extract, Polyglyceryl-6 Caprylate, Polyglyceryl-4 Caprate, Polyglyceryl-4 Cocoate, Polyglyceryl-6 Ricinoleate, Polyglyceryl-4 Laurate/Seba-cate, Polyglyceryl-6 Caprylate/Caprate, Camphor, Arnica Montana Flower Extract, Aloe Barbadensis Leaf Extract, Xanthan Gum, Lavender (Lavandula Hybrida) Oil, Peppermint (Mentha Piperita) Oil, Caprylyl Glyceryl Ether, Caprylhydroxamic Acid

- MADE IN USA NO PEGS
 NON-GMO NO SULFATES
 WOMEN-OWNED NO PARABENS
 GLUTEN FREE NO SYNTHETIC
 & VEGAN FRAGRANCES



This roll-on makes for an easy Warnings 1 application to sore areas, even SAGELY in hard-to-reach spots. The wounds, or damaged, broken, or irritated lightweight formula dissolves skin or with a heating pad. When using this quickly and leaves skin feeling product, avoid contact with eyes or mucous smooth, never greasy. membranes. Do not bandage tightly. Stop PAIN RELIEF use and ask a doctor if condition worsens or **Active ingredient** ROLL-ON if symptoms persist for more than 7 days or Menthol 10% clear up and occur again in a few days. If Directions pregnant or breastfeeding, ask a healthcare Use only as directed. Adults and children professional before use. Keep out of reach affected area and massage into painful **Distributed by Sagely Naturals** than 3 to 4 times daily. Children 12 years **INSTANT COOLING** Santa Monica, CA 90404 or younger: ask a doctor. See carton for additional drug facts. 95% Natural Ingredients LBL - 5000



PAIN RELIEF ROLL-ON

menthol liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82075-420 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|---------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 10 g in 100 g | | |
| | | | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458) | |
| ARNICA MONTANA (UNII: O80TY208ZW) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LAURYL GLUCOSIDE (UNII: 76LN7P7UCU) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311) | |
| BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K) | |
| PROPANEDIOL (UNII: 5965N8W85T) | |
| POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYGLYCERYL-6 CAPRYLATE (UNII: DGV8R54VG7) | |
| POLYGLYCERYL-4 CAPRATE (UNII: 3N873UN885) | |
| POLYGLYCERYL-6 RICINOLEATE (UNII: 8X57R183N7) | |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| WATER (UNII: 059QF0KO0R) | |
| CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T) | |
| COCO-CAPRYLATE (UNII: 4828G836N6) | |
| GLYCERYL STEARATE CITRATE (UNII: WH8T92A065) | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | |
| DIHEPTYL SUCCINATE (UNII: 057N7SS26Y) | |
| FYTIC ACID (UNII: 7IGF0S7R8I) | |
| CAPRYLYL GLYCERYL ETHER (UNII: MI97BW74XZ) | |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) | |

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:82075-420- 20 | 1 in 1 CARTON | 07/02/2021 | | |
| 1 | | 60 g in 1 CYLINDER; Type 0: Not a Combination Product | | | |
| 2 | NDC:82075-420- 05 | 1 in 1 CARTON | 11/19/2021 | | |
| 2 | | 51 g in 1 CYLINDER; Type 0: Not a Combination Product | | | |

| Marketing Information | | | |
|---|---------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348 | 07/02/2021 | |
| | | | |

Labeler - Sagely Enterprises Inc. (117049032)

| Establishment | | | | |
|--------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Verde Cosmetic Labs, LLC | | 080656433 | manufacture(82075-420) | |

Revised: 11/2021 Sagely Enterprises Inc.