

THE RELIEF COMPANY- menthol gel
Symedic 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.

Drug Facts

Active Ingredient

Menthol 2%

Purpose

Topical analgesic

Use

Temporary relief from minor aches and pains of sore muscles & joints associated with

- arthritis
- simple backache
- strains
- bruises
- sprains.

Warnings

For external use only.

When using this product

- Avoid contact with the eye or mucous membranes
- Do not apply to wounds or damaged skin
- Do not use with other ointments, creams, sprays or liniments
- Do not apply to irritated skin or if excessive irritation develops
- Do not bandage
- Wash hands after use with cool water
- Do not use with heating pad or device
- Contains sulfur compounds.

Stop use and ask a doctor if conditions worsen, or if symptoms persist for more than 7 days, or clear up and reoccur.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 12 years of age and older: Spray onto affected areas no more than 4 times daily; massage not necessary. Children under 12 years of age: consult a physician.

Other Information

Store in a cool dry place with lid closed tightly.

Inactive Ingredients

dimethyl sulfone, dimethyl sulfoxide, eucalyptus oil*, hydrogen peroxide, peppermint oil*, spike lavender oil*, water.

Relleve Naturals - Menthol Spray [7140288801]

New

7140288801

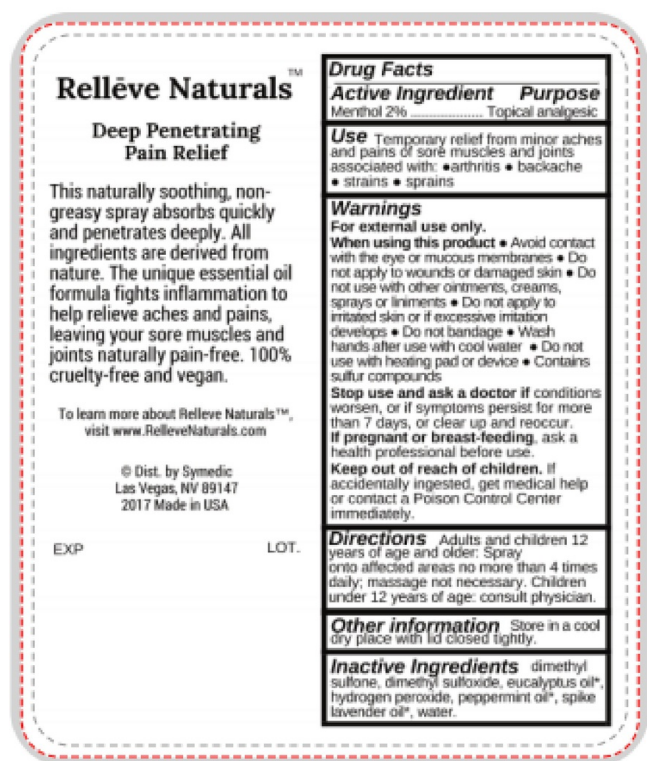
Relleve Naturals

Deep Penetrating Pain Relief

- All-Natural Formula
- Essential Oil Blend
- For Muscle & Joint Pain

Topical Spray

1 fl oz / 30 ml



THE RELIEF COMPANY

menthol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71402-101

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 4 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S) | |
| WATER (UNII: 059QF0K00R) | |
| ARNICA MONTANA (UNII: O80TY208ZW) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71402-101-01 | 89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | 09/03/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 09/03/2019 | |

Labeler - Symedic LLC (060844542)

Revised: 9/2019

Symedic LLC