## 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.

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#### **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 [17140288801]

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



#### Drug Facts Relleve Naturals Active Ingredient Purpose Deep Penetrating Use Temporary relief from minor ache and pains of sore muscles and joints Pain Relief ssociated with: •arthritis • backache strains • sprains This naturally soothing, non-Warnings greasy spray absorbs quickly Warnings For external use only. When using this product • Avoid contact with the eye or mucous membranes • Oo not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays or liminents • Do not apply to initiated skin or if excessive imitation develops • Do not bandage • Wash hands after use with cool water • Do not use with heating pad or device • Contains suffur compounds and penetrates deeply. All ingredients are derived from nature. The unique essential oil formula fights inflammation to help relieve aches and pains, leaving your sore muscles and joints naturally pain-free. 100% cruelty-free and vegan. sulfur compounds sulfur compounces Stop use and ask a doctor if condition 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. To learn more about Relleve Naturals™, visit www.RelleveNaturals.com Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately. © Dist. by Symedic Las Vegas, NV 89147 2017 Made in USA **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 physician. Other information Store in a coo Inactive Ingredients dimethyl one, dimethyl sulfoxide, eucalypt ogen peroxide, peppermint oil\*,

# THE RELIEF COMPANY menthol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71402-101

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 HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
TROLAMINE (UNII: 9O3K93S3TK)			
MELALEUCA ALTERNIFO LIA LEAF (UNII: G43C57162K)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)			
WATER (UNII: 059QF0KO0R)			
ARNICA MONTANA (UNII: O80TY208ZW)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
CAMPHOR (NATURAL) (UNII: N20HL7Q941)			
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/03/2019		

<b>Marketing Inform</b>			
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