RELIEVE AND RELAX PAIN RELIEVING- camphor (synthetic), menthol gel MAC Innovations, LLC

Relieve and Relax Pain Relieving

DRUG FACTS

Active Ingredients

Camphor 4.0% w/w Menthol 10.0% w/w

Purpose

Topical Analgesic

Uses:

Temporarily relieves the minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

Warnings:

- For external use only.
- Flammable, Keep away from fire or flame.
- Avoid getting into eyes or on mucous membranes.
- If conditions worsens, or if symptoms persist for more than 7 days or clear up and occur within a few days, discontinue use of this product and consult a doctor.

Do not use

- on wounds or damaged skin.
- Do not bandage tightly. Caution: Discontinue use if excessive irritation of the skin develops.

Keep out of reach of children.

• Use only as directed. • Do not use if pregnant or breastfeeding. • If swallowed, get medical help or contact a poison control center right away.

Directions:

SHAKE WELL BEFORE USE Adults and children 12 years of age and older: Using the rollon applicator, massage a liberal amount of gel directly on the affected area not more than 3-4 times daily. Children under 12 years of age: Ask a doctor.

Other Information:

Store between 10 and 30°C (50-86°F) Avoid freezing and excessive heat above 32°C (90°F)

Inactive Ingredients:

Acrylates/Beheneth- 25 Methacrylate Copolymer, Caprylyl Glycol, Chondroitin Sulfate, Ethanol SDA 40B, Eucalyptus Oil, Glucosamine Sulfate, Glycerin, Magnesium Chloride, Peppermint Oil, Phenoxyethanol, Propylene Glycol, Triethanolamine, Water

Questions or Comments?

Call Toll Free: 954-747-3300 Monday through Friday 8:30 AM to 5:00 PM EST. Visit us: www.RelieveAndRelax.com email us: info@RelieveAndRelax.com Or Write us: MAC Innovations, LLC Attn: Quality Assurance Dept. 2301 SW 145th Ave. Miramar, FL USA 33027

Package Labeling:

DRUG FACTS (Cont.)

Other Information:

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& JOINT PAIN

RELAXES SPRAINS & STRAINS

3 FL. 0Z. (88.7mL)

DRUG FACTS

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RELIEVE AND RELAX PAIN RELIEVING

camphor (synthetic), menthol gel

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:81790-001

TOPICAL Route of Administration

Active Ingredient/Active Moiety Basis of Ingredient Name Strength Strength CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) -**CAMPHOR** 40 mg UNII:5TJD82A1ET) (SYNTHETIC) in 1 mL 100 mg MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) **MENTHOL** in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
EUCALYPTUS OIL (UNII: 2R040NI662)		
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)		
GLYCERIN (UNII: PDC6A3C0OX)		
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)		

PEPPERMINT OIL (UNII: AV092KU4JH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:81790- 001-00	88.7 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	06/01/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	06/01/2021		

Labeler - MAC Innovations, LLC (079554472)

Revised: 10/2023 MAC Innovations, LLC