

MUSCLE AND JOINT- menthol gel

Kareway Product, 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.

Sound Body Muscle and Joint Rub

Active ingredient

Menthol 2.5%

purpose

Topical analgesic

Uses

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

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on wound s or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

redness over the affected area.

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 symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children

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

Directions

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

camphor, carbomer 940, glycerin, isopropyl alcohol, methylparaben, polysorbate 60, purified water, and trolamine

Questions or Comments?

1-800-833-0085

Package label

Muscle and joint pain relief rub



MUSCLE AND JOINT

menthol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0634

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0634-4	1 in 1 BOX	12/12/2013	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/12/2013	

Labeler - Kareway Product, Inc. (121840057)

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Kareway Product, Inc.