MEDISTIK COOLING ROLL-ON- menthol, camphor solution Medistik 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.

MEDISTIK COOLING ROLL-ON

ACTIVE INGREDIENTS

Menthol 10%

Camphor 4%

PURPOSE

Topical Analgesic

USES

For the temporary relief of sore muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains
- bruises
- cramps

WARNINGS

When using this product

- use only as directed
- avoid getting into the eyes and mucous membranes
- do not bandage tightly or use with a heating pad
- do not apply to wounds or damaged skin

Stop use and ask doctor if

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

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

DIRECTIONS

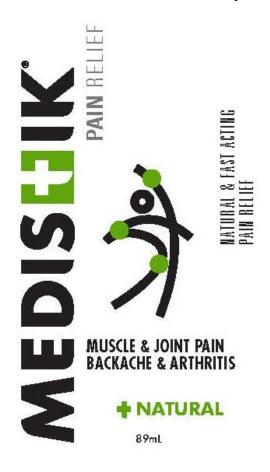
- For use on adults and children over 12 years of age and older: Apply product on affected area, not more than 4 times daily
- children under 12 years of age: ask a doctor

INACTIVE INGREDIENTS

Denatured alcohol, Water, Peppermint oil, Glycerin, Polyacrylate Crosspolymer-6, MSM, Ilex

paraguariensis leaf extract, Glucosamine sulphate, Chondroitin sulphate, Folic acid, Vitamin C, Vitamin D.

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.





ALSO INCLUDES:
MISM
ILEX
GLUCOS AMINE
CHON DROITIN
PEPPERMINT
OIL
FOLIC ACID
VITAMINS
C & D

Greaseless, non-staining, colour and paraben-free



Drug Facts	
Active Ingredients	Purpose
Menthol 10%	Topical Analgesic
Camphor 4%	Topical Analgesic

Uses Temporarily relieves minor aches and pains of muscles and joints associated with ■ simple backache ■ arthritis ■ strains ■ sprains ■ bruises ■ cramps

Warnings For external use only

When using this product ■ use only as directed ■ avoid getting into the eyes and mucous membranes ■ do not bandage tightly or use with a heating pad ■ do not apply to wounds or damaged skin

Stop use and ask doctor if ■ condition worsens
■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ excessive skin irritation or redness occurs

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

Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.

Flammable: Keep away from excessive heat or open flame. Store in a cool dry place with lid or cap closed tightly

Directions wadults and children 12 years of age and older: apply product on affected area, not more than 4 times daily with the under 12 years of age; ask a doctor

Inactive Ingredients Denatured alcohol, Water, Peppermint oil, Glycerin, Polyacrylate Crosspolymer-6, MSM, llex paraguariensis leaf extract, Glucosamine sulphate, Chondrottin sulphate, Folic acid, Vitamin C, Vitamin D

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MEDISTIK COOLING ROLL-ON

menthol, camphor solution

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77108-103		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	10 g in 100 mL	
CAMPHOR OIL (UNII: 75IZZ8 Y727) (CAMPHOR OIL - UNII:75IZZ8 Y727)	CAMPHOR OIL	4 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
WATER (UNII: 059QF0KO0R)			
PEPPERMINT OIL (UNII: AV092KU4JH)			

GLYCERIN (UNII: PDC6A3C0OX)
AMMONIUM ACRYLO YLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (4500 MPA.S) (UNII: Q7UI015FF9)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
GLUCO SAMINE SULFATE (UNII: 1FW7WLR731)
CHONDROITIN SULFATE (CHICKEN) (UNII: 7VZ9466BAB)
FOLIC ACID (UNII: 935E97BOY8)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
VITAMIN D (UNII: 9 VU1KI44GP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 1	NDC:77108-103-11	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
Marketing Information				
N	Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ОТ	C monograph not fi	nal part348	05/14/2020	

Labeler - Medistik Inc (204132562)

Revised: 5/2020 Medistik Inc