

COLD SPOT POINT RELIEF- menthol ointment

Pure Source

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.

Cold Spot Point Relief Pain relieving Roll On - 3 oz.

Active Ingredients: Menthol

Inactive Ingredients: deionized water, arnica, chondroitin sulfate, citric acid, eucalyptus oil, glucosamine sulfate, ilex paraguariensis leaf, isopropyl alcohol, peppermint oil, dimethyl sulfone, polysorbate-20, SD alcohol 40B.

Keep out of reach of children. If swallowed consult physician

Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

Use: For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.

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Apply directly to effected area. Do not use more than four times per day.

ColdSpot Point Relief Pain Relieving spray, all natural ingredients.

Drug Facts	
Active Ingredient: menthol - USP 14%	Purpose: external analgesic
Uses: For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.	
Warnings:	
<ul style="list-style-type: none"> • For external use only • Avoid contact with eyes • Do not apply to open wounds or damaged skin • If symptoms persist for more than seven days, discontinue use and consult physician • Keep out of reach of children. If swallowed, consult physician • Do not bandage tightly 	
Directions: Apply directly to effected area. Do not use more than four times per day.	
Other Ingredients: aqua (deionized water), arnica montana flower (arnica) extract, boswellia serrata extract, carbomer, chondroitin sulfate, eucalyptus globulus oil, glucosamine sulfate, glycyrrhiza glabra (licorice) extract, ilex paraguariensis leaf (yerba mate) extract, mentha piperita (peppermint) oil, methylisothiazolinone, MSM (dimethyl sulfone), polysorbate -20, SD-alcohol 40B, triethanolamine	

Manufactured by: PURE SOURCE, Inc.
9750 NW 17th Street
Miami, FL 33172
(305) 477-8111

soothing menthol relief

ColdSpot™
POINT RELIEF™

pain relieving roll-on

all natural ingredients

really hits the spot

net wt. 3 fl.oz./90mL



FABRICATION ENTERPRISES INC.
made in USA

CE

Authorized CE representative:
RIMS UK Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU (UK)
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COLD SPOT POINT RELIEF

menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13 mL in 90 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
CARBOMER 1342 (UNII: 809Y72KV36)	

peppermint oil (UNII: AV092KU4JH)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-002-03	90 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	08/24/2010		

Labeler - Pure Source (969241041)

Registrant - Pure Source (969241041)

Establishment			
Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture