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, citirc acid, euclayptus oil, glucosamine sulfate, ilex paraguariesis 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: 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.

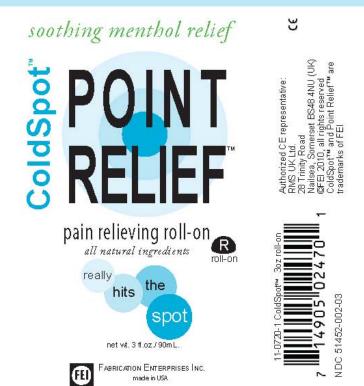
Warnings:

- · 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, boswella serrata extract, carbomer, chondroitin sulfate, eucalyptus globulus oil, glucosamine sulfate, glycrrhiza 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



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: 059QF0KO0R)		
ARNICA CORDIFOLIA FLOWER (UNII: JCG10SZ7A8)		
CHONDROITIN SULFATE (BOVINE) (UNII: 6 IC1M3OG5Z)		
EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6 E6)		
GLUCO SAMINE SULFATE (UNII: 1FW7WLR731)		
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)		
CARBOMER 1342 (UNII: 809 Y72KV36)		

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

F	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	

Revised: 8/2010 Pure Source