COLD SPOT POINT RELIEF- menthol aerosol, spray 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 Spray - 2 oz. Spray

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: menthol - USP 10% 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.

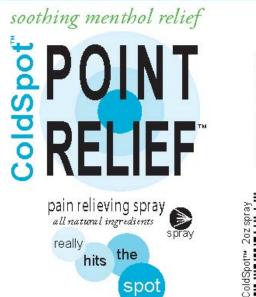
Warnings:

- · 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 useand 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: a qua (deionized water), arnica montana flower (arnica) extract, chondroitin sulfate, citricacid, eucalyptus globulus oil, glucosamine sulfate, ilex paraguariensis leaf (yerba mate') extract, isopropyl alcohol, mentha piperita (peppermint) oil, MSM (dimethyl sulfone), polysorbate -20, SD-alcohol 40B

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





FABRICATION ENTERPRISES INC. made in USA

net wt. 2 fl.oz./60m L.



COLD SPOT POINT RELIEF

menthol aerosol, spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65121-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthMenthol (UNII: L7T10 EIP3A) (Menthol - UNII:L7T10 EIP3A)Menthol6 mL in 60 mL

Inactive Ingredients

 Ingredient Name
 Strength

 water (UNII: 059QF0KO0R)

ARNICA CORDIFOLIA FLOWER (UNII: JCG10SZ7A8)

CHONDROITIN SULFATE (BOVINE) (UNII: 6 IC1M3OG5Z)

Citric Acid (UNII: 2968PHW8QP)

EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6 E6)

Glucosamine sulfate (UNII: 1FW7WLR731)

ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
Isopropyl Alcohol (UNII: ND2M416302)	
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:65121-003-02	60 mL in 1 BOTTLE, SPRAY				

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: 9/2010 Pure Source