

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 - 4 oz. Spray

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.

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

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

Cold Point Relief pain relieving spray. All natural ingredients

Drug Facts**Active Ingredients:** 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 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), amica montana flower (arnica) extract, chondroitin sulfate, citric acid, 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

soothing menthol relief

ColdSpot™

POINT
RELIEF™

pain relieving spray 

all natural ingredients

really hits the spot

net wt. 4fl.oz. / 120mL.

 FABRICATION ENTERPRISES INC.
made in USA

Authorized CE representative:
 RMS UK Ltd.
 28 Trinity Road
 Nailsea, Somerset BS48 4NU (UK)
 ©FEI 2010, all rights reserved
 ColdSpot™ and Point Relief™ are trademarks of FEI

CE

11-0701-1 ColdSpot™ 4oz spray

7 14905102479 4

NDC 65121-003-04

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 Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	12 mL in 120 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
Arnica cordifolia flower (UNII: JCG1OSZ7A8)	
Chondroitin sulfate (bovine) (UNII: 6IC1M3OG5Z)	

Citric Acid (UNII: 2968PHW8QP)	
Eucalyptus Globulus leaf (UNII: S546YLW6E6)	
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:65121-003-04	120 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: 8/2010

Pure Source