

COLD SPOT POINT RELIEF- menthol, methyl salicylate gel

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. gel

Active ingredients: MENTHOL, METHYL SALICYLATE

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:	Purpose:
menthol -USP 12%	external analgesic
methyl salicylate 4%	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, bromelain, carbomer, diazolidinyl urea, eucalyptus globulus oil, glycyrrhiza glabra (licorice) extract, ilex paraguariensis leaf (yerba mate') extract, mentha piperita (peppermint) oil, methyl paraben, MSM (dimethyl sulfone), polysorbate-80, propyl paraben, propylene glycol, 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 gel 
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)
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11-0730-1 ColdSpot™ 4oz gel
7 14905 02430 5
NDC 51452-001-04

COLD SPOT POINT RELIEF

menthol, methyl salicylate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	14 mL in 120 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	5 mL in 120 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
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:65121-001-04	120 mL in 1 TUBE		

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