

## **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.*

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### **Cold Spot Point Relief Pain relieving Spray - 2 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.

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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.

<b>Drug Facts</b>	
<b>Active Ingredient:</b> menthol - USP 10%	<b>Purpose:</b> external analgesic
<b>Uses:</b> For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.	
<b>Warnings:</b>	
<ul style="list-style-type: none"> <li>+ For external use only</li> <li>+ Avoid contact with eyes</li> <li>+ Do not apply to open wounds or damaged skin</li> <li>+ If symptoms persist for more than seven days, discontinue use and consult physician</li> <li>+ Keep out of reach of children. If swallowed, consult physician</li> <li>+ Do not bandage tightly</li> </ul>	
<b>Directions:</b> Apply directly to effected area. Do not use more than four times per day.	
<b>Other Ingredients:</b> aqua (deionized water), arnica 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. 2 fl.oz. / 60mL.

FED FABRICATION ENTERPRISES INC.  
made in USA

Authorized CE representative:  
RIMS UK Ltd.  
28 Trinity Road  
Nailsea, Somerset BS48 4NU (UK)  
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11-0700-1 ColdSpot™ 2oz spray  
7 14905 02476 3  
NDC 51452-003-02

## COLD SPOT POINT RELIEF

menthol aerosol, spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65121-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	6 mL in 60 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>ARNICA CORDIFOLIA FLOWER</b> (UNII: JCG1OSZ7A8)	
<b>CHONDROITIN SULFATE (BOVINE)</b> (UNII: 6IC1M3OG5Z)	
<b>Citric Acid</b> (UNII: 2968PHW8QP)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)	
<b>Glucosamine sulfate</b> (UNII: 1FW7WLR731)	

<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>Isopropyl Alcohol</b> (UNII: ND2M416302)	
<b>Peppermint Oil</b> (UNII: AV092KU4JH)	
<b>Dimethyl Sulfone</b> (UNII: 9H4PO4Z4FT)	
<b>polysorbate 20</b> (UNII: 7T1F30V5YH)	
<b>alcohol</b> (UNII: 3K9958V90M)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-003-02	60 mL in 1 BOTTLE, SPRAY		

<b>Marketing Information</b>			
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)

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