

## **COLD SPOT POINT RELIEF- menthol 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.*

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### **Cold Spot Point Relief Pain relieving Gel - 16 oz.**

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.

pain relieving gel.

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.

ColdSpot Point Relief Pain Relieving spray, all natural ingredients.


<b>Drug Facts</b>	
<b>Active Ingredients:</b> menthol - USP 12% methyl salicylate 4%	<b>Purpose:</b> external analgesic 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> • 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	
<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, 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. 1.6fl. oz / 480ml.



FABRICATION ENTERPRISES INC.  
made in USA

Authorized CE representative:  
RMS UK Ltd.  
28 Trinity Road  
Nailsea, Somerset BS48 4NU (UK)  
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11-0710-1 ColdSpot™ 1.6oz gel



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NDC 51452-001-16

## COLD SPOT POINT RELIEF

menthol gel

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	58 mL in 480 mL
MENTHYL SALICYLATE (UNII: 43XOA705ZD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MENTHYL SALICYLATE	19 mL in 480 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CARBOMER 1342 (UNII: 809Y72KV36)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Eucalyptus Globulus LEAF (UNII: S546YLW6E6)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
Ilex Paraguariensis LeaF (UNII: 1Q953B4O4F)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
Peppermint Oil (UNII: AV092KU4JH)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-001-16	480 mL in 1 CONTAINER		

### 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