

# 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 Gel - 32 oz.

Active Ingredients: Menthol, methyl salicylate

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.

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.

Drug Facts	
<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> <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, boswellia 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.  
2750 NW 17h 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. 32fl. oz. / 960mL.

FABRICATION ENTERPRISES INC.  
made in USA

Authorized CE representative:  
RMS UK Ltd.  
28 Trinity Road  
Nailsea, Somerset BS48 4NU (UK)  
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11-0711-1 ColdSpot™ 32oz. gel

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NDC 51452-001-32

menthol, methyl salicylate 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

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	115 mL in 960 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	38 mL in 960 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
water (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CARBOMER 1342 (UNII: 809Y72KV36)	
Ilex Paraguariensis LeaF (UNII: 1Q953B4O4F)	
Eucalyptus Globulus LEAF (UNII: S546YLW6E6)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
Peppermint Oil (UNII: AV092KU4JH)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65121-001-32	960 mL in 1 CONTAINER		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	08/24/2010	

**Labeler** - Pure Source (969241041)

**Registrant** - Pure Source (969241041)

### Establishment

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

