

## COLD SPOT POINT RELIEF- menthol, methyl salicylate gel Fabrication Enterprises

*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 - 4 oz.

Active Ingredients: Menthol, methyl salicylate

Inactive Ingredients: deionized water, arnica, chondroitin sulfate, citirc acid, euclayptus oil, glucosamine sulfate, ilex paraguayensis 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.

Use: 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 affected 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 paraguayensis leaf (yerba mate) extract, mentha piperita (peppermint) oil, methyl paraben, MSM (dimethyl sulfone), polysorbate-80, propyl paraben, propylene glycol, SD-alcohol 40B, triethanolamine	

Manufactured For:  
Fabrication Enterprises Inc.  
Post Office Box 1500  
White Plains, New York 10602 USA  
tel: 914-345-9300 fax: 914-345-9800  
www.FabricationEnterprises.com

soothing menthol relief

**ColdSpot** **POINT RELIEF**  
pain relieving gel  
all natural ingredients

really hits the spot

net wt. 4fl. oz. / 120mL

FEB FABRICATION ENTERPRISES, INC.  
made in USA

Authorized CE representative:  
PWS UK Ltd  
11-0730-1 ColdSpot™ 4oz gel  
Naissea Somerset BS48 4NU (UK)  
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11-0730-1 ColdSpot™ 4oz gel  
7 14905-02430 5  
NDC 61452-001-04

**COLD SPOT POINT RELIEF**

menthol, methyl salicylate gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51452-001
<b>Route of Administration</b>	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)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-001-04	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** - Fabrication Enterprises (070577218)

**Registrant** - Fabrication Enterprises (070577218)

### Establishment

Name	Address	ID/FEI	Business Operations
Fabrication Enterprises		070577218	relabel

## Establishment

Name	Address	ID/FEI	Business Operations
pure source		969241041	manufacture

Revised: 10/2010

Fabrication Enterprises