# COLD SPOT POINT RELIEF- menthol aerosol, spray 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.

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

Active Ingredients: Menthol

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

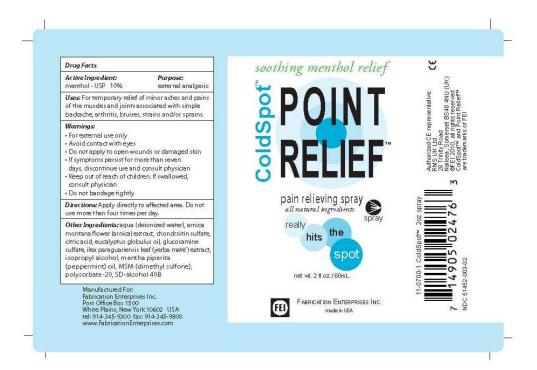
Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

pain relieving spray

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.



#### COLD SPOT POINT RELIEF

menthol aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51452-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	6 mL in 60 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
ARNICA CORDIFOLIA FLOWER (UNII: JCG10SZ7A8)		
CHONDROITIN SULFATE (BOVINE) (UNII: 6 IC1M3OG5Z)		
Citric Acid (UNII: 2968 PHW8 QP)		
EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6E6)		
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)		

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-003-02	60 mL in 1 BOTTLE, SPRAY		

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	<b>Business Operations</b>	
Fabrication Enterprises		070577218	relabel	

## Establishment

Name	Address	ID/FEI	Business Operations
pure source		969241041	manufacture

Revised: 10/2010 Fabrication Enterprises