

**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.

Cold Spot Point Relief Pain relieving Spray - 16 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.

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.

Drug Facts	
Active Ingredients: menthol - USP 10%	Purpose: external analgesic
Uses: For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.	
Warnings:	
<ul style="list-style-type: none"> • 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 	
Directions: Apply directly to affected area. Do not use more than four times per day.	
Other Ingredients: 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 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 spray

all natural ingredients

really

hits

the

spot

net wt. 1.6fl.oz. / 480mL.

Authorized CE representative:

RMS UK Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU (UK)
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11-0702-1 ColdSpot™ 1.6oz spray

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NDC 51452-003-16

FABRICATION ENTERPRISES INC.
made in USA

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	48 mL in 480 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
Citric Acid (UNII: 2968PHW8QP)	

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)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-003-16	480 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	Business Operations
fabrication enterprises		070577218	relabel

Establishment			
Name	Address	ID/FEI	Business Operations
pure source		969241041	manufacture