

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 - 4 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.

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.
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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. 4fl. oz. / 120mL

FEI FABRICATION ENTERPRISES INC.
made in USA

Authorized CE representative:
RMS UK Ltd
28 Timby Road
Mallesa, Somerset BS48 4NU (UK)
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11-0701-1 ColdSpot™ 4oz spray
7 14905102479 4
NDC 51482-003-04

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	12 mL in 120 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
Citric Acid (UNII: 2968PHW8QP)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
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:51452-003-04	120 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

Revised: 10/2010

fabrication enterprises