

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 - 16 oz.

Active Ingredients: Menthol, methyl salicylate

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 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	
Active Ingredients: menthol - USP 12% methyl salicylate 4%	Purpose: external analgesic 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: • 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, 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 For:
Fabrication Enterprises Inc.
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www.FabricationEnterprises.com

soothing menthol relief

ColdSpot™

POINT RELIEF™

pain relieving gel

all natural ingredients

really hits the spot

net wt. 1.6 fl. oz./48ml.

FABRICATION ENTERPRISES INC.
made in USA

Authorized CE representative: **CC**
RMS UK Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU (UK)
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11-0710-1 ColdSpot™ 1.6oz gel

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NDC 51452-001-16

COLD SPOT POINT RELIEF

menthol, methyl salicylate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51452-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	58 mL in 480 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	19 mL in 480 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CARBOMER 1342 (UNII: 809Y72KV36)	

DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
Eucalyptus Globulus LEAF (UNII: S546YLW6E6)
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)
Ilex Paraguariensis LeaF (UNII: 1Q953B4O4F)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
Peppermint Oil (UNII: AV092KU4JH)
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)
polysorbate 80 (UNII: 6OZP39ZG8H)
ALCOHOL (UNII: 3K9958V90M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-001-16	480 mL in 1 BOTTLE		

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