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 paraguariesis leaf, isopropyl alcohol, peppermint oil, dimethyl sulfone, polysorbate-20, SD alcohol 40B.

Keep out of reach of children. If swallowed consult physician

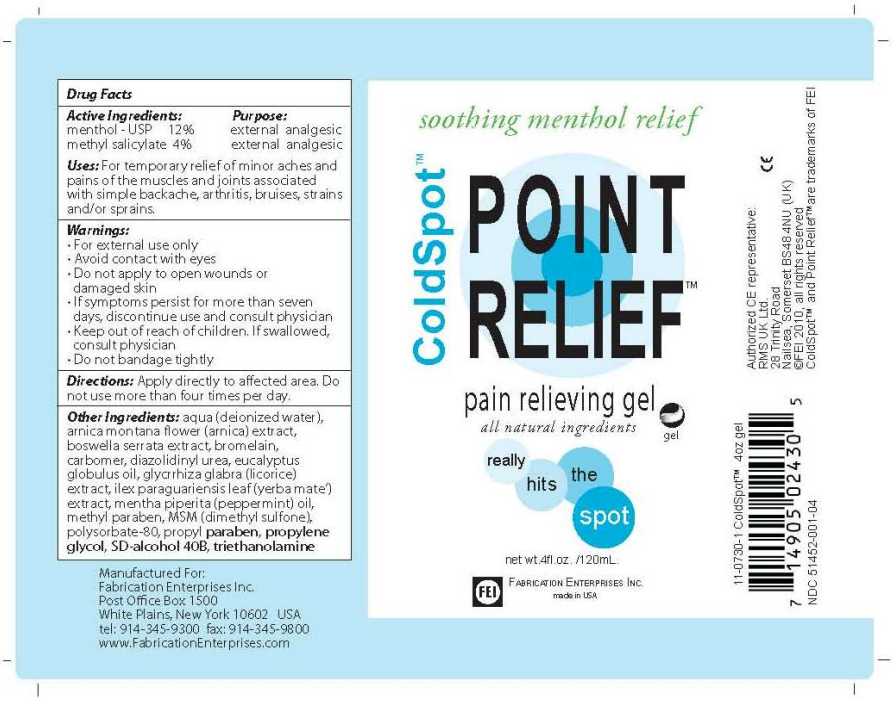
Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

pain relieving 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.



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	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

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