COLD SPOT POINT RELIEF - menthol gel
Fabrication Enterprises, inc.

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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coldspot point relief

menthol - usp 12%

methyl salicylate 4%

aqua (deionized water), arnica montana flower (arnica) extract, boswella serrata extract, brtomelain, carbomer, diazolidinyl urea, eucalyptus globulus oil, glycrrhiza glabra (licorice) extract, ilex paraguariensis leaf (yerba mate) extract, menth piperita (pepperment) oil, methyl paraben, MSM (dimethyl sulfone) polysorbate-80, SD-alcohol 40B, triethanolamine

Keep out of reach of children. If swallowed, consult physician.

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

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 affected area. do not use more than four times per day.

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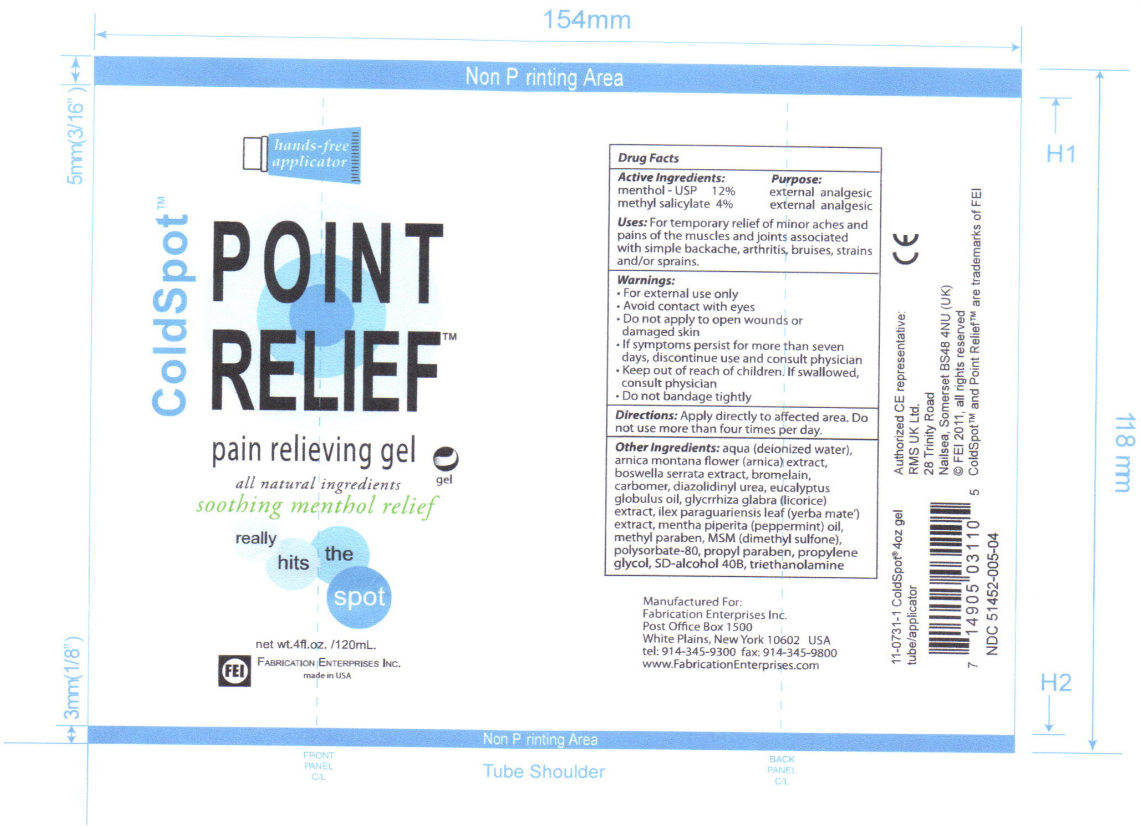

COLD SPOT POINT RELIEF

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	14.4 mL in 120 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4.8 mL in 120 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BOSWELLIA SERRATA RESIN OIL (UNII: 5T1XCE6K8K)	
BROMELAINS (UNII: U182GP2CF3)	
CARBOMER 1342 (UNII: 809Y72KV36)	
Eucalyptus Globulus leaf (UNII: S546YLW6E6)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
Peppermint Oil (UNII: AV092KU4JH)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
alcohol (UNII: 3K9958V90M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51452-005-04	4 mL in 1 TUBE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/13/2011	

Labeler - Fabrication Enterprises, inc. (070577218)

Registrant - Pure Source (969241041)

Establishment

Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture

Revised: 10/2011

Fabrication Enterprises, inc.