

COLD SPOT POINT RELIEF- menthol ointment 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 Roll On - 3 oz.

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

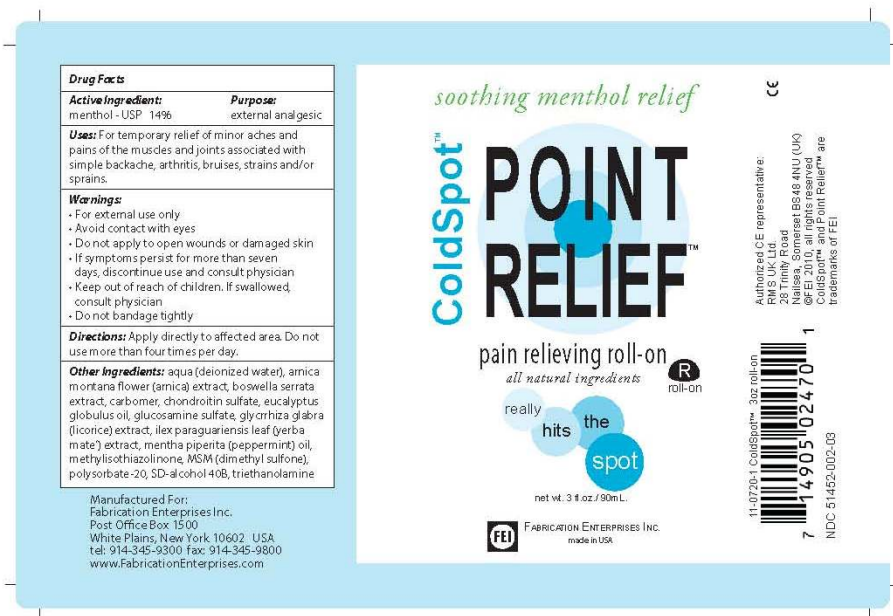
Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

pain relief

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 ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51452-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	13 mL in 90 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
CARBOMER 1342 (UNII: 809Y72KV36)	
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:51452-002-03	90 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

