COLD SPOT POINT RELIEF- menthol, methyl salicylate gel Pure Source

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 - 32 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

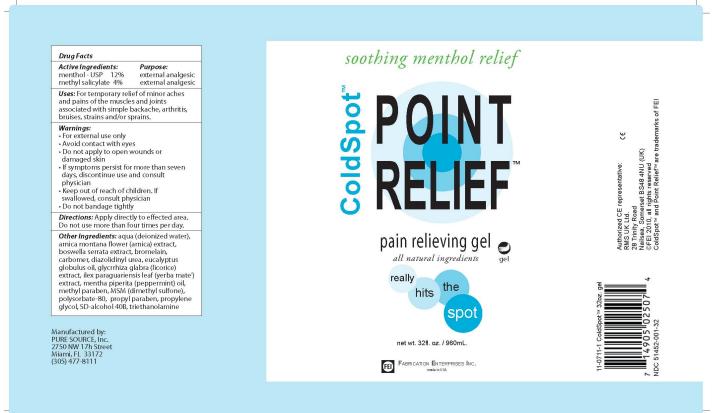
Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

pain relieving gel.

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.



menthol, methyl salicylate gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	115 mL in 960 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	38 mL in 960 mL	

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
ARNICA CORDIFOLIA FLOWER (UNII: JCG10SZ7A8)		
CARBOMER 1342 (UNII: 809 Y72KV36)		
Ilex Paraguariensis LeaF (UNII: 1Q953B4O4F)		
Eucalyptus Globulus LEAF (UNII: S546 YLW6 E6)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)		
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:65121-001-32	960 mL in 1 CONTAINER		

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/24/2010	

Labeler - Pure Source (969241041)

Registrant - Pure Source (969241041)

Establishment			
Name	Address	ID/FEI	Business Operations
Pure Source		969241041	manufacture

Revised: 8/2010 Pure Source