

COLD SPOT POINT RELIEF- menthol 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 - 1 Gallon

Active Ingredients: Menthol

Inactive Ingredients: deionized water, arnica, chondroitin sulfate, citirc acid, euclayptus oil, glucosamine sulfate, ilex paraguayensis 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.

Use: For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains and/or sprains.

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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 5.0% 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: <ul style="list-style-type: none">- 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 effected area. Do not use more than four times per day.	
Other Ingredients: aqua (deionized water), arnica montana flower (arnica) extract, boswellia serrata extract, boswellatin, carthamus diandrolifolius, euclayptus globulus oil, glycyrrhiza glabra (licorice) extract, ilex paraguayensis leaf (yerba mate) extract, mentha piperita (peppermint) oil, methyl paraben, BSG (dimethyl sulfone), polysorbate 80, propyl paraben, propylene glycol, SD alcohol 40B, triethanolamine	

Manufactured by:
PURE SOURCE, Inc.
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COLD SPOT POINT RELIEF

menthol 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	0.46 L in 3.8 L

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
ARNICA CORDIFOLIA FLOWER (UNII: JCG1OSZ7A8)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
Citric Acid (UNII: 2968PHW8QP)	
Eucalyptus Globulus Leaf (UNII: S546YLW6E6)	
Glucosamine sulfate (UNII: 1FW7WLR731)	
Ilex Paraguariensis Leaf (UNII: 1Q953B4O4F)	
Isopropyl Alcohol (UNII: ND2M416302)	
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:65121-001-28	3.8 L in 1 BOTTLE, PUMP		

Marketing Information

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