HOT SPOT POINT RELIEF- capsaicin 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.

Hot Spot Point Relief Pain relieving gel - 8 oz.

Active Ingredients: Capsaicin

Inactive Ingredients: deionized water, oil of Cassia, chondroitin sulfate, glucosamine sulfate, Glycrrhiza Glabra (licorice) extract, Carbomer, Triethanolamine, polysorbate-20, Phenoxyethanol, Ethylhexylglycrine.

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.

HotSpot Point Relief Pain Relieving gel, all natural ingredients.

Drug Facts

Active Ingredient: Purpose 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:

- · 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

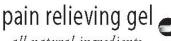
Directions: Apply directly to effected area. Do not use more than four times per day.

Other Ingredients: aqua (deionized water), oil of cassia, chondroitin sulfate, glucosamine sulfate, glycrrhiza glabra (licorice) extract, carbomer, triethanolamine, polysorbate-20, phenoxyethanol, ethylhexylglycerin

Manufactured by: PURE SOURCE, Inc. 9750 NW 17th Street Miami, FL 33172 (305) 477-8111







all natural ingredients



net wt.8fl. oz./ 240mL



FABRICATION ENTERPRISES INC. made in USA

Authorized CE representative: (CE RMS UK Ltd.
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Nailsea, Somerset BS48 4NU (UK)
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710781-1 HotSpot™ 8oz.gel

HOT SPOT POINT RELIEF

capsaicin gel

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65121-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	1.5 mL in 240 mL

Inactive Ingredients

Ingredient Name Strength

polysorbate 20 (UNII: 7T1F30 V5YH) CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z) Glucosamine sulfate (UNII: 1FW7WLR731) GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) CARBOMER 1342 (UNII: 809Y72KV36) PHENOXYETHANOL (UNII: HIE492ZZ3T)	water (UNII: 059QF0KO0R)	
Glucosamine sulfate (UNII: 1FW7WLR731) GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) CARBOMER 1342 (UNII: 809Y72KV36)	polysorbate 20 (UNII: 7T1F30V5YH)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) CARBOMER 1342 (UNII: 809Y72KV36)	CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
CARBOMER 1342 (UNII: 809 Y72KV36)	Glucosamine sulfate (UNII: 1FW7WLR731)	
	GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	CARBOMER 1342 (UNII: 809 Y72KV36)	
	PHENO XYETHANOL (UNII: HIE492ZZ3T)	

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-010-08	240 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	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