HOT SPOT POINT RELIEF- capsaicin gel
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.

Hot Spot Point Relief Pain relieving gel - 3 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

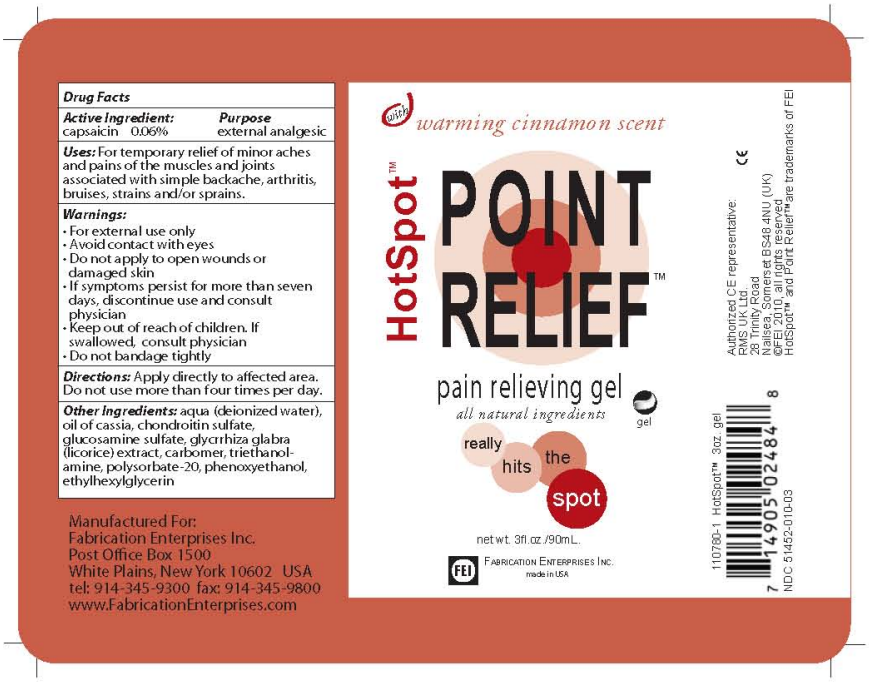
Warnings Section: For external use only, avoid contact with eyes, do not apply to open wounds or damaged skin, if symptoms persist for more than seven days discontinue use and consult physician, keep out of reach of children and if swallowed consult physician, do not bandage tightly.

Pain relieving gel

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.

HotSpot Point Relief Pain Relieving gel, all natural ingredients.



PRINTING INSTRUCTIONS

Image is 4.75" x 3.625" with a .125" bleed on all four sides

The rounded corners have a radius of .0625

Print on coated label stock in:

Black
Pantone 1807 C

HOT SPOT POINT RELIEF

capsaicin gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.5 mL in 90 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
polysorbate 20 (UNII: 7T1F30V5YH)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
Glucosamine sulfate (UNII: 1FW7WLR731)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CARBOMER 1342 (UNII: 809Y72KV36)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51452-010-03	90 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 - 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