

**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 - 32 oz.

Active Ingredients: Capsaicin

Inactive Ingredients: deionized water, oil of Cassia, chondroitin sulfate, glucosamine sulfate, Glycyrrhiza 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 10.25" x 6" with a .125" bleed on all four side
 The rounded corners have a radius of .0625
 Print on coated label stock in: Black, and Pantone 1807 C

Drug Facts	
Active Ingredient: capsaicin 0.06%	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:	
<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 affected area. Do not use more than four times per day.	
Other Ingredients: aqua (deionized water), oil of cassia, chondroitin sulfate, glucosamine sulfate, glycyrrhiza glabra (licorice) extract, carbomer, triethanolamine, polysorbate-20, phenoxyethanol, ethylhexylglycerin	

Manufactured For:
 Fabrication Enterprises Inc.
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 White Plains, New York 10602 USA
 tel: 914-345-9300 fax: 914-345-9800
 www.FabricationEnterprises.com

The packaging design features a red and white color scheme. At the top, it says "warming cinnamon scent". The brand name "HotSpot" is written vertically in red, and "POINT RELIEF" is in large black letters. Below this, it says "pain relieving gel" and "all natural ingredients". A graphic shows the words "really hits the spot" in red circles. At the bottom, it says "net wt. 32fl. oz. / 960mL." and includes the FEI logo and "FABRICATION ENTERPRISES INC. made in USA".

Authorized CE representative: RMS UK Ltd. 28 Trinity Road Nailsea, Somerset BS48 4NU (UK) ©FEI 2010, all rights reserved HotSpot™ and Point Relief™ are trademarks of FEI

11-0782-1 HotSpot™ 32oz. gel
 7 114905 02489 3
 NDC 51452-010-32

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	5.8 mL in 960 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:51452-010-32	960 mL in 1 BOTTLE, PUMP		

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

Revised: 10/2010

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