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 - 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.

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.

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.

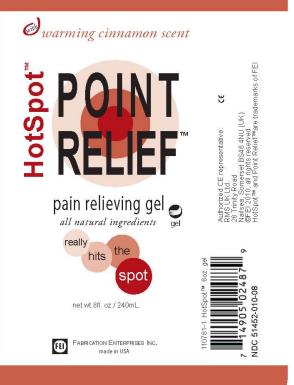
Warnings:

- For external use onlyAvoid 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, glycrrhiza glabra (licorice) extract, carbomer, triethanolamine, polysorbate-20, phenoxyethanol, ethylhexylglycerin

Manufactured For: Padridactured For: Fabrication Enterprises Inc. Post Office Box 1500 White Plains, New York 10602 USA tel: 914-345-9300 fax: 914-345-9800 www.FabricationEnterprises.com



PRINTING INSTRUCTIONS

Image is 5.75" x 4.875" 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

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	1.5 mL in 240 mL

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

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-010-08	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 - 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 fabrication enterprises