POINT RELIEF COLD SPOT PAIN RELIEVING- menthol 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.

Point Relief Cold Spot Pain Relieving Gel

Drug Facts

Active Ingredients:

menthol - USP 12%

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 sevan days, discontinue use and consult physician

Keep out of reach of children

- If swallowed, consult physician
- Do not bandage tightly

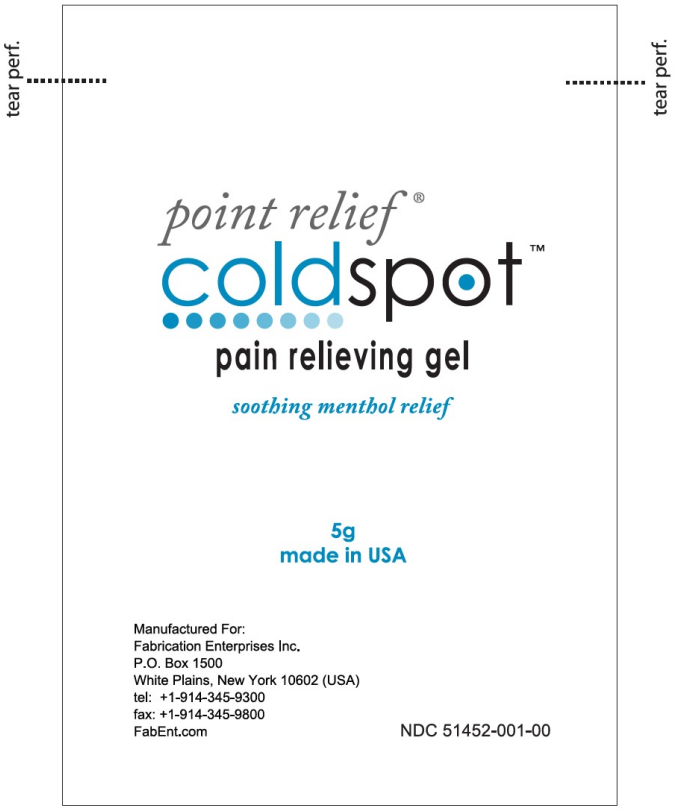
Directions:

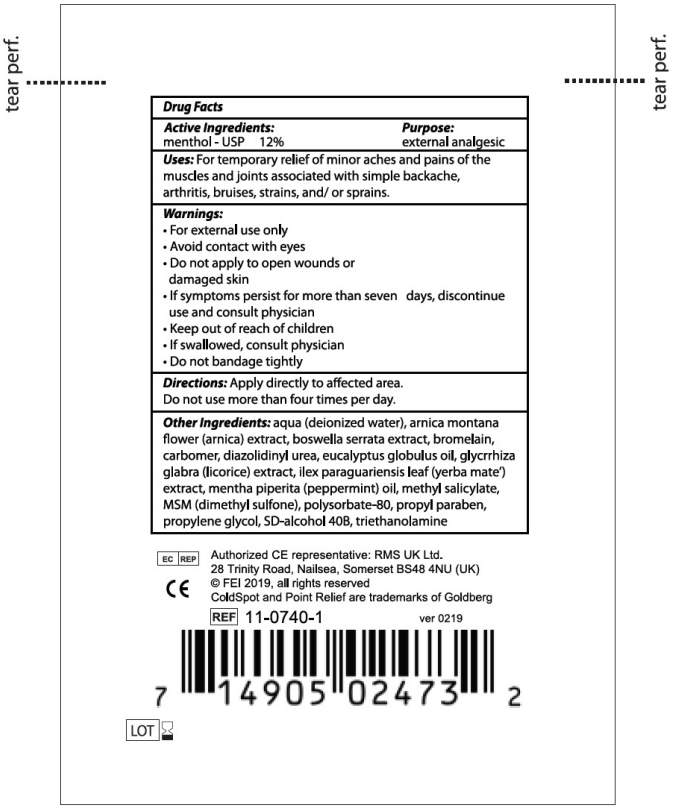
Apply directly to affected area. Do not use more than four fimes per day.

Other Ingredients:

aqua (deionized water), arnica montana flower (arnica) extract, boswellia serrata extract, bromelain, carbomer, diazolidinyl urea, eucalyptus globulus oil, glycyrrhiza glabra (licorice) extract, ilex paraguariensis leaf (yerba mate) extract, mentha piperita (peppermint) oil, methyl salicylate, MSM (dimethyl sulfone), polysorbate-80, propyl paraben, propylene glycol, SD-alcohol 40B, triethanolamine

Package Labeling:





POINT RELIEF COLD SPOT PAIN RELIEVING

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51452-036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	120 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
BROMELAINS (UNII: U182GP2CF3)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-036-06	5 g in 1 PACKET; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/01/2019	

Labeler - Fabrication Enterprises (070577218)

Revised: 4/2019 Fabrication Enterprises