

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 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), 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

Point Relief Cold Spot Pain Relieving Gel, 120mL (51452-035-01)

Non Printing Area

LOT  

point relief[®]
coldspot[™]
pain relieving gel
soothing menthol relief

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: <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), arnica montana flower (arnica) extract, boswella 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	

EC REF

CE

Authorized CE representative:
RMS UK Ltd.
28 Trinity Road
Nailsea, Somerset BS48 4NU (UK)
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REF 11-0730-1

7 14905024305
NDC 51452-001-04 ver 0119

4 fl oz / 120 ml
made in USA

Manufactured For:
Fabrication Enterprises Inc. tel: +1-914-345-9300
P.O. Box 1500 fax: +1-914-345-9800
White Plains, New York 10602 (USA) FabEnt.com

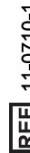
Non Printing Area

Point Relief cold Spot Pain Relieving Gel, 475mL (51452-035-02)

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:	
<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), arnica montana flower (arnica) extract, boswella 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	

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 pain relieving gel
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7 NDC 51452-001-16 ver 0219

Manufactured for:
 Fabrication Enterprises Inc tel: +1-914-345-9300
 PO BOX 1500 fax: +1-914-345-9800
 White Plains, NY 10602 (USA) FabEnt.com

**16 fl oz / 475 ml
 made in USA**

Point Relief cold Spot Pain Relieving Gel, 3.8L (51452-035-03)

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:	
<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), arnica montana flower (arnica) extract, boswella 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	

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7 NDC 51452-001-128 ver 0219

Manufactured for:
 Fabrication Enterprises Inc tel: +1-914-345-9300
 PO BOX 1500 fax: +1-914-345-9800
 White Plains, NY 10602 (USA) FabEnt.com

**1 gal / 3.8 L
 made in USA**

Point Relief cold Spot Pain Relieving Gel, 420mL(Hands Free)(51452-035-04)

Non Printing Area



point relief[®]
coldspot[™]
pain relieving gel
soothing menthol relief

Drug Facts

Active Ingredients:	Purpose:
menthol - USP 12%	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 affected area. Do not use more than four times 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

Authorized CE representative:

RMS UK Ltd.

28 Trinity Road

Nailsea, Somerset BS48 4NU (UK)



REF 11-0731-1



NDC 51452-005-04

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ver 0219

4 fl oz / 120 ml
made in USA

Manufactured For:
Fabrication Enterprises Inc.
P.O. Box 1500
White Plains, New York 10602 (USA)
tel: +1-914-345-9300
fax: +1-914-345-9800
FabEnt.com

Non Printing Area

FRONT
PANEL
C/L

Tube Shoulder

BACK
PANEL
C/L

Point Relief cold Spot Pain Relieving Gel, 950mL (51452-035-05)

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:	
<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), 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	

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 pain relieving gel
soothing menthol relief

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REF 11-0711-1



NDC 51452-001-32 ver 02/19

Manufactured for:
 Fabrication Enterprises Inc tel: +1-914-345-9300
 PO BOX 1500 fax: +1-914-345-9800
 White Plains, NY 10602 (USA) FabEnt.com

32 fl oz / 950 ml
made in USA



POINT RELIEF COLD SPOT PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51452-035
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 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	

INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
BROMELAINS (UNII: U182GP2CF3)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
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:51452-035-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
2	NDC:51452-035-02	475 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
3	NDC:51452-035-03	3800 mL in 1 JUG; Type 0: Not a Combination Product	04/01/2019	
4	NDC:51452-035-04	420 mL in 1 TUBE; Type 0: Not a Combination Product	04/01/2019	
5	NDC:51452-035-05	950 mL in 1 BOTTLE; 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)