

**POINT RELIEF COLD SPOT PAIN RELIEVING ROLL-ON- menthol liquid**  
**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.*

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**Point Relief cold Spot Pain Relieving roll-on**

***Drug Facts***

***Active Ingredients:***

menthol - USP 14%

***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, carbomer, chondroitin sulfate, eucalyptus globulus oil, glucosamine sulfate, glycyrrhiza glabra (licorice) extract, ilex paraguariensis leaf (yerba mate) extract, mentha piperita (peppermint) oil, methylisothiazolinone, MSM (dimethyl sulfone), polysorbate-20, SD-alcohol 40B, triethanolamine

***Package Labeling:***

Drug Facts	
<b>Active Ingredients:</b> menthol - USP 14%	<b>Purpose:</b> external analgesic
<b>Uses:</b> For temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, bruises, strains, and/ or sprains.	
<b>Warnings:</b>	
<ul style="list-style-type: none"> <li>• For external use only</li> <li>• Avoid contact with eyes</li> <li>• Do not apply to open wounds or damaged skin</li> <li>• If symptoms persist for more than seven days, discontinue use and consult physician</li> <li>• Keep out of reach of children</li> <li>• If swallowed, consult physician</li> <li>• Do not bandage tightly</li> </ul>	
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*point relief*<sup>®</sup>  
**coldspot**<sup>™</sup>  
 pain relieving roll-on  
*soothing menthol relief*

Authorized CE representative:  
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REF 11-0720-1  
 EC REF  
 CE  
 14905 02470 1  
 NDC 51452-002-03 ver 0119

**Manufactured for:**  
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**3 fl oz / 90 ml**  
**made in USA**

## POINT RELIEF COLD SPOT PAIN RELIEVING ROLL-ON

menthol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51452-037
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	140 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)

POLYSORBATE 20 (UNII: 7T1F30V5YH)

TROLAMINE (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51452-037-06	90 mL in 1 CONTAINER; 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

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