

**COLD AND HOT CVS- menthol 7.6% methyl salicylate 29.0% spray
CVS**

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.

Active ingredients

Menthol 7.60%
Methyl Salicylate 29.00%

Purpose

Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with: • arthritis • simple backache • muscle strains
• bruises • sprains

Warnings

For external use only.

Flammable • keep away from fire or flame • do not use while smoking or near heat or flame • avoid long term storage above 104°F. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120°F.

When using this product • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged skin • do not bandage tightly • use only as directed

Stop use and ask doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • needed for longer than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get help or contact a Poison Control Center right away.

Directions

• shake well • adults and children 2 years of age and older:
spray product on affected area, not more than 3 to 4 times
daily. • children under 2 years of age: consult a doctor

Inactive ingredients

Alcohol Denat.
Arnica Montana Flower Extract

Boswellia Serrata Gum Extract
 Dimethyl Sulfone
 Eucalyptus Globulus Leaf Oil
 Ilex Paraguariensis Leaf Extract
 Mentha Piperita (Peppermint) Oil
 Olea Europaea (Olive) Fruit Oil
 Propylene Glycol
 Water

Drug Facts

Active ingredients	Purpose
Menthol 7.6%	Topical Analgesic
Methyl Salicylate 29.0%	Topical Analgesic

Uses • temporarily relieves minor pain of muscles and joints associated with: • arthritis • simple backache • strains • bruises • sprains

Warnings

For external use only.

Flammable: Do not use while smoking or near heat or flame

Do not use • in the eyes

When using this product • keep out of eyes • do not bandage tightly • do not use with a heating pad • use only as directed • do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Ask a doctor before use if you have

- deep or puncture wounds • animal bites • serious burns

Stop use and ask doctor if • Condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • needed for longer than 1 week

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • shake well • adults and children 12 years of age and older: Spray product on the area, not more than 1 to 3 times daily. • children under 12 years of age: consult a doctor

Other information May cause staining. Use with caution when spraying near fabrics and unprotected surfaces.

Inactive ingredients Alcohol Denat., Arnica Montana Flower Extract, Boswellia Serrata Gum Extract, Dimethyl Sulfone, Eucalyptus Globulus Leaf Oil, Ilex Paraguariensis Leaf Extract, Mentha Piperita (Peppermint) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Water.



Compare to the active ingredients in **Icy Hot® Pain Relieving Balm***

Cold & Hot

SORE MUSCLE SPRAY

MENTHOL 7.6%
METHYL SALICYLATE 29.0%

- Pain relief therapy for arthritis, backache, muscle strains & sprains
- Non-greasy
- Quick drying




NET WT 4 OZ (113 g)

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Icy Hot®.



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COLD AND HOT CVS

menthol 7.6% methyl salicylate 29.0% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-269
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	7.6 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	29.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-269-04	113 g in 1 CAN; Type 0: Not a Combination Product	11/13/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/13/2014	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(59779-269)