

COLD AND HOT SCHERER LABS- menthol 7.6% methyl salicylate 29.0% spray
Product Quest Mfg, LLC

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.

Drug Facts

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




Cool 'N Heat

Pain Relieving Continuous Spray

Menthol 7.6% & Methyl Salicylate 29.0% / Topical analgesic
 Penetrates on the Spot for Soothing Relief
 Sprays at any Angle




NET WT 3.8 OZ (109 g)



Since 1933, Scherer Labs™ has been providing Quality, Innovative and Value oriented family-care products.

Drug Facts	Purpose
Active ingredients	
Menthol 7.6%.....	Topical analgesic
Methyl Salicylate 29.0%.....	Topical analgesic
Uses • temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • bruises • muscle sprains	
Warnings For external use only.	
Flammable • 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	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • shake well • adults and children 12 years of age and older: spray product on affected area, not more than 3 to 4 times daily. • children under 12 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.	

Manufactured by:
 Product Quest Mfg, LLC.
 330 Carswell Ave.
 Daytona Beach, FL 32117
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COLD AND HOT SCHERER LABS

menthol 7.6% methyl salicylate 29.0% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64048-3334
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	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:64048-3334-4	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 - Product Quest Mfg, LLC (927768135)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(64048-3334)

Revised: 5/2018

Product Quest Mfg, LLC