COLD AND HOT SCHERER LABS- menthol 7.6% mehyl 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.

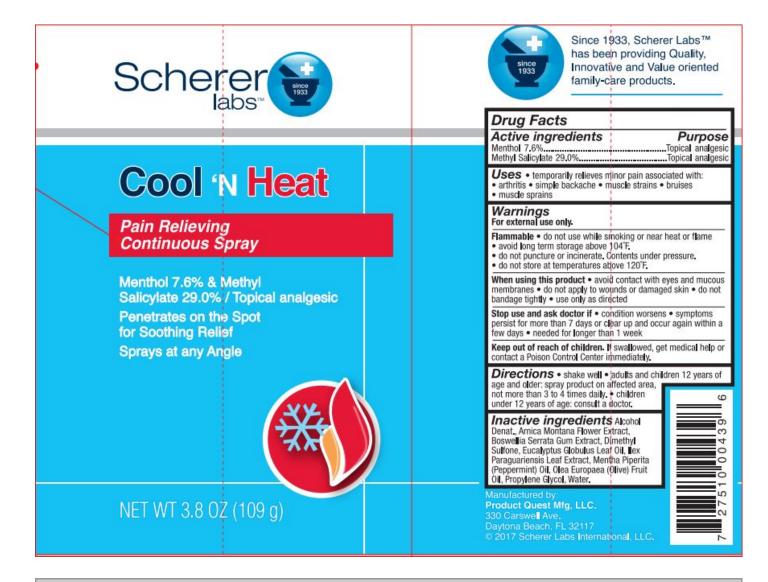
If swallowed, get help or contact a Poison Control Center right away.

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



COLD AND HOT SCHERER LABS

menthol 7.6% mehyl 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 Streng	gth Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHO L	7.6 g in 100 g		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) METHYL SALI				ATE 29.0 g in 100 g		
Inactive Ingredie	nts					
	Ingredient Name			Strength		
ARNICA MONTANA F						
INDIAN FRANKINCEN	SE (UNII: 4PW41QCO2M)					
EUCALYPTUS OIL (UNII: 2R04ONI662)						
DIMETHYL SULFONE	(UNII: 9H4PO4Z4FT)					
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)						
PEPPERMINT OIL (UN	III: AV092KU4JH)					
WATER (UNII: 059QF0	KO0R)					
ALCOHOL (UNII: 3K99	958V90M)					
OLIVE OIL (UNII: 6 UY	K2W1W1E)					
Propylene Glycol (UN	I: 6DC9Q167V3)					
Packaging						
# Item Code	Package Description	Marke	ting Start Date M	farketing End Date		
1 NDC:64048-3334-4	113 g in 1 CAN; Type 0: Not a Combination Product	11/13/20	14			
Marketing Info	rmation					
0			hading Chart Data	Markeding End Date		
Marketing Categor			-	Marketing End Date		
OTC monograph not fin	al 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