COOL N HEAT- cool n heat spray NeilMed Pharmaceuticals, Inc.

Cool n Heat

ACTIVE INGREDIENT PURPOSE

Menthol 16% Topical analgesic

Uses

Temporality alleviates minor aches and pains of muscles and joints associated with Arthritis, Simple Backache, Strains, Bruises, or Sprains

Warnings:

For external use only.

Flammable: Do not use while smoking or near heat or flames. 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 or symptoms persist for more than 7 days or clear up and occur again within a few days. Do not use for longer than 1 week. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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

Directions:

Shake well – adults and children 12 year 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:

Glycerin, propylene Glycol, SD Alcohol 40 (58%), USP grade purified Water.

Dosage and Administration

Shake well

adults and children 12 years of age and older spray on affected area not more than 3 to 4 times daily

children under 12 years of age consult a doctor

Indication & Usage

temporarily relief of pain and itching associated with arthritis simple backache muscle strains bruises cramps muscle sprains

OTC - Keep Out of Reach of Children

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

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

OTC Purpose Section

temporarily relief of pain and itching associated with:

arthritis • simple backache • muscle strains • bruises • cramps • muscle sprains

Cool 'n heat, 16% Menthol/Pain relieving Spray



cool n heat spray

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:13709-311

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	160 mg in 1 mL

Inactive Ingredients

Ingredient Name
Strength

GLYCERIN (UNII: PDC6A3C0OX)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:13709-311- 01	118 mL in 1 CAN; Type 0: Not a Combination Product	11/09/2018			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	11/09/2018			

Labeler - NeilMed Pharmaceuticals, Inc. (799295915)

Revised: 1/2024 NeilMed Pharmaceuticals, Inc.