DCH COOL AND HEAT- menthol 16% spray Derma Care Research Labs, 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.

DCH Cool and Heat Spray, 16% Menthol

Menthol 16%

Topical Analgesic

For the temporary relief of minor aches and pain associated with arthritis, simple backache, muscle strains, bruises, and sprains.

For external use only. Flammable--Keep away from fire or flame. **When using this product** avoid contact with eyes. In case of contact with eyes, flush thoroughly with water, do not apply to wounds or damaged skin, and do not bandage tightly, do not use with a heating pad. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120F. . **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 12 years of age: ask a doctor.

Alcohol Denat., Glycerin, Propylene Glycol, Water



DCH COOL AND HEAT

menthol 16% spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		

GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:72839-129- 04	113 g in 1 CAN; Type 0: Not a Combination Product	02/12/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/12/2021	
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Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment				
Name	Address	ID/FEI	Business Operations	
Derma Care Research Labs, LLC		116817470	manufacture(72839-129)	

Revised: 6/2023 Derma Care Research Labs, LLC