

DCH LABS COOL AND HEAT ROLL-ON- menthol 16% liquid
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 Labs Cool & Heat Roll-On

Menthol 16%

External Analgesic

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

For external use only. Flammable--Keep away from fire or flame. **When using this product** avoid contact with eyes, do not apply to wounds or damaged skin, and do not bandage tightly. **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.

Clean affected area before applying product. 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 old ask a doctor.

Acrylates/C10-30 alkyl acrylate crosspolymer, alcohol denat., glycerin, phenoxyethanol, propylene glycol, water, xanthan gum.

Drug Facts

Active ingredient Menthol 16%.....	Purpose External Analgesic
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Uses For the temporary relief of minor pain associated with • arthritis • simple backache • muscle strains • sprains • bruises • cramps.

Warnings
Flammable - Keep away from fire or flame.
For external use only.
When using this product • keep out of eyes • do not apply to wounds or damaged skin • do not bandage tightly.
Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days • redness or irritation develops.
Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions • clean affected area before applying product • adults and children 12 years and older, apply to affected area not more than 3 to 4 times daily • Children under 12 years old, ask a doctor.

Other information • store at 15°C - 30°C

Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Alcohol Denat., Glycerin, Phenoxyethanol, Propylene Glycol, Water, Xanthan Gum.



DCH LABS

Cool & Heat Roll-On

Medicated

Menthol 16%

Temporary Pain Relief for
Arthritis, Backache,
Muscle Strains & Sprains

Non Greasy
Quick Drying

* Compare to active ingredient in IcyHot®
Net Wt. 2.5 oz (71 g)

*This product is not manufactured or distributed by Chatterm, Inc.®, owner of the registered trademark IcyHot®



Manufactured by:
DermaCare Research Labs, LLC
440 Fentress Blvd., Daytona Beach, FL 32114

DCH LABS COOL AND HEAT ROLL-ON
menthol 16% liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-101
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)			
ALCOHOL (UNII: 3K9958V90M)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-101-02	71 g in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/16/2021	

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(72839-101)

Revised: 12/2021

Derma Care Research Labs, LLC