QC COOL AND HEAT ROLL-ON- menthol 16% liquid
Chain Drug Marketing Association Inc

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.

QC 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.

QC COOL AND HEAT ROLL-ON

menthol 16% liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-511
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:63868-511-02	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 - Chain Drug Marketing Association Inc (011920774)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(63868-511)

Revised: 1/2023 Chain Drug Marketing Association Inc