

**COLD AND HOT PAIN RELIEVING CAREONE- menthol 16.00% liquid
CareOne**

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 ingredient	Purpose
Menthol 16%.....	Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • sprains • bruises

For external use only.

When using this product • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes and mucous membranes • do not apply to wounds or damaged, broken or irritated skin • if you experience pain, swelling, or blistering of the skin where an OTC topical muscle and joint pain reliever was applied, stop using the product and seek medical attention immediately. These products should not cause pain or skin damage.

Stop use and ask doctor if • condition worsens • redness is present • irritation develops • symptoms persist for more than 7 days or clear up and occur again within a few days

Flammable • keep away from fire or flame

Keep out of reach of children.

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

Directions

Adults and children over 12 years: • apply to affected area but no more than 3 to 4 times daily • IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER.
Children 12 years or younger: ask a doctor

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Capsaicin, Glycerin, Isopropyl Myristate, Propylene Glycol, SD Alcohol 40 (30%), Triethanolamine, Water

Compare to the active ingredient in Icy Hot® No Mess Applicator

CAREONE®

**MAXIMUM STRENGTH
COLD & HOT
PAIN RELIEVING LIQUID**

Menthol 16%

NO MESS APPLICATOR

- Long-lasting pain relief
- Dries rapidly • Stain-free

**2.5 FL OZ
(73 mL)**

ACTUAL SIZE



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DISTRIBUTED BY
FOODHOLD U.S.A., LLC
LANDOVER, MD 20785

1-877-846-9949

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COLD AND HOT PAIN RELIEVING CAREONE

menthol 16.00% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-777	
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 mL	
Inactive Ingredients				
Ingredient Name				Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
Capsaicin (UNII: S07O44R1ZM)				
Glycerin (UNII: PDC6A3C0OX)				
Isopropyl Myristate (UNII: 0RE8K4LNJS)				
Propylene Glycol (UNII: 6DC9Q167V3)				
ALCOHOL (UNII: 3K9958V90M)				
TROLAMINE (UNII: 9O3K93S3TK)				
Water (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-777-03	1 in 1 CARTON	07/14/2015	
1		73 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/14/2015		

Labeler - CareOne (809183973)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(41520-777) , label(41520-777)