ICY COOL MAXIMUM STRENGTH - menthol gel
C.D.M.A. 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.

DRUG FACTS

Active Ingredient

Natural Menthol 5.5%

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis,
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

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
- a transient burning sensation may occur upon application but generally disappears in several days.

Stop use and ask a 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 of flame

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

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

Directions

Adults and children over 12 years:

- apply generously to affected area
- message into painful area until thoroughly absorbed into skin
- repeat as necessary, 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 –

Aloe Barbadensis Leaf Extract, Carbomer, FD&C Blue #1, Glycerine USP, Ilex Paraguariensis Extract, Isopropyl Alcohol USP, Camphor, Propylene Glycol USP, Methyl Paraben, Purified Water, Silicon Dioxide, Tocopheryl Acetate (Vitamin E Acetate), Triethanolamine

Principal Display Panel - 3 oz. Roll on Label

QC Quality Choice

NDC 63868-632-82

*Compare to BIOFREEZE®
Pain Relieving Gel

Maximum Strength

Icy Cool™ with aloe

Pain Relieving Roll-On

Natural Menthol 5.5% | Topical Analgesic

Relief From Aches and Pains Associated with Strains, Sprains, Backaches, Bruises and Arthritis

1 Roll-on 3oz./89mL.

MORE Active Ingredient than BIOFREEZE®*

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QUALITY CHOICE

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MORE Active Ingredient than BIOFREEZE®*

Close cap tightly after use.

SATISFACTION 100% GUARANTEED

Distributed by C.D.M.A., Inc.©
43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300

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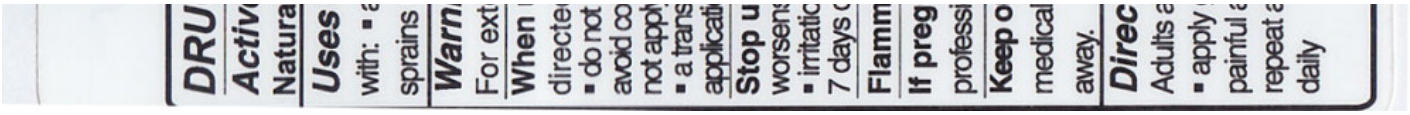
*This product is not manufactured by or for Total Health, Inc. Corp. registered owner of the registered trademark BIOFREEZE®



ICY COOL MAXIMUM STRENGTH

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-632
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	55 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63868-632-82	89 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

Labeler - C.D.M.A. Inc. (011920774)

Registrant - NATURAL ESSENTIALS, INC. (947484713)

Establishment

Name	Address	ID/FEI	Business Operations
NATURAL ESSENTIALS INC.		947484713	MANUFACTURE(63868-632)

Revised: 8/2014 C.D.M.A. Inc.