

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 or flame

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

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 generously to affected area
- massage 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 –

AloeVera, Carbomer, FD&C Blue #1, Glycerine USP, Ilex Paraguariensis Extract, Isopropyl Alcohol USP, Camphor, Propylene Glycol USP, Methyl Paraben, Purified Water, Silicon Dioxide, Triethanolamine, Vitamin E

Principal Display Panel - 4 oz. Tube Label

QC Quality Choice

NDC 63868-0633-18

*Compare to BIOFREEZE®

Pain Relieving Gel

Maximum Strength

Icy Cool™

Pain Relieving Gel

Natural Menthol 5.5% | Topical Analgesic

Relief From:

Aches and pains associated with strains, sprains, backaches, bruises and arthritis

With Aloe

1 Tube 4oz./118ml.

NDC 63868-0633-18

*Compare to BIOFREEZE® Pain Relieving Gel



Maximum Strength

ICY COOL™

Pain Relieving Gel

Natural Menthol 5.5% | Topical Analgesic

Relief from:

Aches and pains associated with strains, sprains, simple backache, bruises and arthritis



1 Tube 4oz./118ml.

MORE Active Ingredient than BIOFREEZE®*

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Close cap tightly after use.



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

ICY COOL MAXIMUM STRENGTH

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-633
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 HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYL PARABEN (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:63868-633-18	118 mL in 1 TUBE		

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(63868-633)