NATURES CHOICE COOL HOT ICE- menthol gel
Unipack, 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.

Active Ingredient

Active Ingredients	Purpose
Menthol 2%	External Pain Reliever

Purpose

External Pain Reliever

Uses

Temporarily relief of minor pains of muscles and joints associated with - simple back ache - arthritis - sprains, strains, or bruises

Warnings

Warnings

For external use only. Avoid contact with eyes

Do not use

Do not use - internally - with heating pad or devices - on wounds or damaged skin

Ask a doctor before use

Ask doctor before use if you have sensitive skin

When using this product

When using this product - Use only as directed - do not bandage tightly - avoid contact with eyes and mucus membranes

If pregnant or breast-feeding

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

Keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

-Adult and children 2 years of age and older. Clean skin thoroughly. Apply liberally to affected area no more than 3-4 times daily. No protective cover needed.

-May be used with ice packs

-May be used with wet or dry bandages, but wrap loosely

-Children under 2 years of age, consult a doctor

Other information

Other information store between 59°□ - 86°□F (15°□ - 30°□C)

Keep tightly closed

Do not use, pour, spill, or store near heat or open flame

Other ingredients

Camphor, Carbomer 940, FDC Blue #1, Isopropyl alcohol, Propylene glycol, Purified water, Sodium hydroxide

Product Label

NATURES CHOICE COOL HOT ICE

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43749-320
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43749-320-08	226 g in 1 JAR	09/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/18/2014	

Labeler - Unipack, Inc. (009248480)

Establishment

Name	Address	ID/FEI	Business Operations
Unipack, Inc.		009248480	manufacture(43749-320)