## ICE COLD ANALGESIC - menthol gel Personal Care Products

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.

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Ice Cold analgesic		
Active Ingredients:		
Menthol 1%		
Purpose		
Topical analgesic		
Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.		
Uses for the temporary relief of minor aches and pains in muscles and joints associated with: simple backache		
sports injuries		
strains		
arthritis		
sprains		
bruises		
Warnings For external use only Do not use with other topical pain relievers, with heating pads or heating devices When using this product do not use in or near eyes, do not apply to wounds or damaged skin do not bandage tightly Stop use and ask doctor if condition worsens, symptoms last more than days or clear up and occur again within a few days, redness or irritation develops		
If pregnant or breast feeding ask a health professional before use.		

Directions

Clean affected area before applying product

adults and children 2 years of age and older; apply to affected area not more than 3-4 times daily

Inactive ingredients carbomer, isopropyl alcohol, kathon CG, sodium hydroxide, thymol, water (aqua), FD and C blue no.1



PCP COPY

Personal Care
Ice cold
analgesic gel
New wt. 8 oz. (227 g)

## ICE COLD ANALGESIC

menthol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9034	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.27 g in 227 g

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
THYMOL (UNII: 3J50XA376E)			
WATER (UNII: 059QF0KO0R)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9034-6	227 g in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/01/2011		

## Labeler - Personal Care Products (966155082)

## Registrant - Personal Care Products (966155082)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Ningbo Liyuan Daily Chemical Products Co Ltd		530766098	manufacture

Revised: 8/2011 Personal Care Products