ICE COLD ANALGESIC GEL- menthol and camphor gel
Universal Distribution Center LLC

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 Ingredients

Menthol 1.0%

Camphor 0.5%

Purpose

Topical Analgesic

Uses

for the temporary relief of minor aches and pains in muscles and joints associated with:

- simple backache
- strains
- sprains
- sports injuries
- arthritis
- 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 7 days or clean up and occur again within a few days
- redness or irritation develops

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

Keep out of the reach of children

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

Directions

- clean affected area before applying product
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

Inactive ingredients

benzyl alcohol, butylated hydroxytoluene, carbopol, colour brillient blue, creasmer RH 40, disodium EDTA, isopropyl alcohol, propylene glycol, purified water and sodium hydroxide

PRINCIPAL DISPLAY PANEL

ICE COLD ANALGESIC GEL

Topical Analgesic
NET WT.8 OZ (227g)

ICE COLD ANALGESIC GEL

menthol and camphor gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER 934 (UNII: Z135WT9208)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-013-17	127 g in 1 TUBE		
2	NDC:52000-013-18	170 g in 1 TUBE		
3	NDC:52000-013-13	170 g in 1 BOTTLE, PLASTIC		
4	NDC:52000-013-14	227 g in 1 BOTTLE, PLASTIC		
5	NDC:52000-013-15	300 g in 1 BOTTLE, PLASTIC		
6	NDC:52000-013-16	500 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/15/2013	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-013)

Revised: 3/2013 Universal Distribution Center LLC