ICE COLD ANALGESIC- menthol gel
North & South Wholesalers 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.

Ice Cold Analgesic Gel

Active Ingredient

Menthol 1.25%

Purpose

Topical Analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
- arthritis
- simple backache
- strains
- bruises
- sports injuries
- sprains
- provides cooling penetrating relife

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 the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a 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
- children under 2 years of age: ask a doctor

Other information

- store at controlled room temperature 20 to 25°C (68 to 77°F) in a tightly closed container.

- do not use, pour, spill or store near heat or open flame.

Inactive Ingredients

benzyl alcohol, BHT, camphor, carbopol, disodium EDTA, FD&C blue no.1, isopropyl alcohol, PEG-40 hydrogenated castor oil, propylene glycol, sodium hydroxide, water.

PRINCIPAL DISPLAY PANEL

ICE COLD ANALGESIC GEL

Topical Analgesic

NET WT.8 OZ (227g)

ICE COLD ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70201-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70201-005-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/19/2018	

Labeler - North & South Wholesalers LLC (004948495)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(70201-005)

Revised: 8/2018 North & South Wholesalers LLC