

UNIVERSAL ICE COLD ANALGESIC- menthol gel
Universal Distribution Center LLC

UNIVERSAL ICE COLD ANALGESIC GEL

Active Ingredients

Menthol 1.25%

Purpose

Topical Analgesic

Uses

Temporary relieves of minor aches and pains in muscles and joints associated with

- arthritis
- simple backache
- strains
- bruises
- sports injuries
- sprains
- provides cooling penetrating relief

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 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

Water, Propylene glycol, Isopropyl alcohol, Carbomer, Sodium hydroxide, Benzyl alcohol, Edetate Disodium, Butylated hydroxytoluene, Camphor, Fd&c Blue No. 1

PRINCIPAL DISPLAY PANEL

ICE COLD
ANALGESIC GEL
8 FL.OZ (227 GRAM)

NET WT. 8 OZ. (227g)
Dist. by **Universal Distribution Center**
GUJ/COS/GC/32/1374
Edison, NJ. IN24840

6 76979 24840 0

ICE COLD
ANALGESIC GEL

muscle pain sports injuries
arthritis sprains

Drug Facts

Active ingredient Menthol 1.25%
Purpose Topical Analgesic

Uses temporarily relieves minor aches and pains of muscles and joints associated with:
■ sprains ■ sports injuries ■ sprains ■ provides cooling penetrating relief

Warnings For external use only
■ Do not use with other topical pain relievers or 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 clear 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 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 Water, Propylene Glycol, Isopropyl Alcohol, Carbomer, Sodium Hydroxide, Benzyl Alcohol, Edetate Disodium, Butylated Hydroxytoluene, Camphor, F&c Blue No. 1

UNIVERSAL ICE COLD ANALGESIC

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
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:52000-105-01	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/25/2020	

Labeler - Universal Distribution Center LLC (019180459)