PERSONAL CARE ICE COLD ANALGESIC- menthol gel
Delta Brands & Products 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 ingredient

Menthol 1.25%

Purpose

Topical Analgesic

Uses

■ temporarily relieves minoraches and pains of 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 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 clear up and occur again within a few days ■ redness or irritation develops

Keep out of reach of children

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

■ stroe 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 oi, propylene glycol, sodium hydroxide, water

Package Label

PERSONAL CARE ICE COLD ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72133-210
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72133-210-08	227 g in 1 JAR; Type 0: Not a Combination Product	04/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/02/2018	

Labeler - Delta Brands & Products LLC (080999173)

Revised: 4/2018 Delta Brands & Products LLC