THERAPEUTIC ICE- menthol 2.00% gel
TopCare

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.

Drug Facts

Active ingredient	**Purpose**
Menthol 2%	External Analgesic

Uses

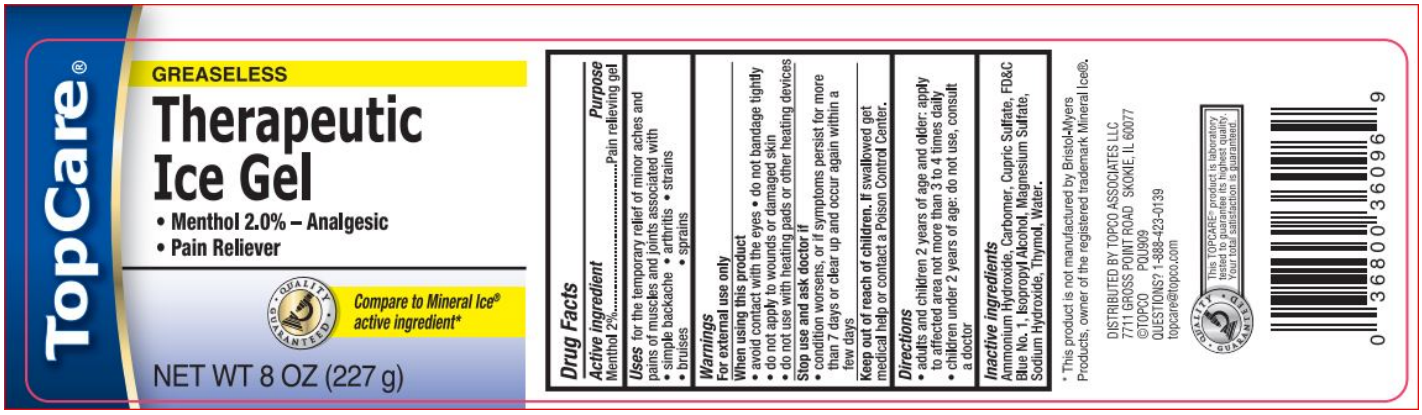
For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

Warnings
For external use only
When using this product • avoid contact with eyes • do not bandage tightly • do not apply to wounds or damaged skin • do not use with a heating pad
Stop use and ask doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions
• for adults & children 2 years of age and older
• cleanse and dry skin
• apply to affected area not more than 3 to 4 times daily
• children under 2 years of age, consult a doctor

Inactive ingredients

Ammonium Hydroxide, Carbomer, Cupric Sulfate, FD&C Blue No. 1, Isopropyl Alcohol, Magnesium Sulfate, Purified Water, Sodium Hydroxide, Thymol.



THERAPEUTIC ICE

menthol 2.00% gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-879
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
Cupric Sulfate (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
Isopropyl Alcohol (UNII: ND2M416302)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
WATER (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Thymol (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-879-06	227 g in 1 JAR; Type 0: Not a Combination Product	03/21/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/21/2012	

Labeler - TopCare (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-879) , label(36800-879)

Revised: 6/2018 TopCare