

ICE QUAKE MUSCLE RUB- menthol gel
Gadal Laboratories Inc

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	Purpose
Menthol 2.0%	Topical Anagesic

Purpose

Topical Analgesic

Uses

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

Warnings

For external use only

When using this product

- Avoid contact with the eyes
- do not bandage tightly
- do not apply to wounds or damaged skin
- do not use with heating pads or ther heating devices

Stop use and ask a 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 immediately.

Directions

- 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; do not use, consult doctor

Inactive ingredients carbomer, propylene glycol, methylparaben, isopropyl alcohol, triethanolamine, FD&C Blue #1, water



ICEQUAKE MUSCLE RUB

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-108
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
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
Water (UNII: 059QF0K00R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-108-08	228 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

Labeler - Gadal Laboratories Inc (841305639)

