

ICE QUAKE- menthol gel
Southern Sales & Service, 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.

Ice Quake

Drug Facts

Active Ingredient

Menthol 15%

PURPOSE

Topical Analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises
- cramps

Warnings

For external use only.

When using this product

- Use only as directed
- Do not bandage tightly
- Do not use with a heating devices
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds, damaged, broken or irritated skin
- If severe burning sensation occurs, discontinue use immediately
- Do not expose the area treated with product to heat or direct sunlight.

Stop use and ask a doctor if:

- condition worsens
- redness is present
- irritation develops

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 18 years:

- apply to affected area
 - squeeze desired amount of **ICEQUAKE** onto affected area
 - massage dispensed gel into painful area until thoroughly absorbed
 - repeat as necessary, but no more than 3 to 4 times daily.
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- **IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER**

Inactive Ingredients

HPMC, Glycerine, FD&C blue #1, Carbopol, Isopropyl alcohol, Propylene glycol, Methylparaben, Sodium hydroxide, Purified water.

Distribute By:**SSS Group, LLC**

Pembroke Pines

FL 33332

Questions or Comments

Call 1 800.213.9370

ICE QUAKE (MENTHOL)

LOT#: EXP:



DISTRIBUTED BY: Southern Sales Services Inc. Pembroke Pines, FL 33332
Questions or Comments? Call 1800.213.9370
icequakeonline.com



ICEQUAKE®

Menthol 15%

Pain Relieving GEL

Net Wt. 4 oz (113 g)

Drug Facts

Active ingredients	Purpose
Menthol 15%.....	Topical Analgesic

Uses
Temporary relieves minor pain associated with:
 ■ Arthritis ■ Simple backache ■ Strains ■ Sprains ■ Bruises

Warnings
 For external use only. Avoid contact with eyes.
 When using this product ■do not bandage tightly ■do not apply to wounds or damaged skin.
 Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days.
 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
 Adults and children 18 years of age and older: apply to affected area not more than 3 to 4 times daily.
 Children under 18 years of age: consult a doctor.

Inactive ingredients glycerine, FD&C blue no. 1, carbopol, hydroxypropyl methylcellulose, isopropyl alcohol, propylene glycol, methylparaben, sodium hydroxide, purified water.

ICEQUAKE menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69822-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16.95 g in 113 g

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
Glycerin (UNII: PDC6A3C0OX)	
FD&C Blue NO. 1 (UNII: HBR47K3TBD)	
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0K00R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Methylparaben (UNII: A28C7HI9T)	
Isopropyl Alcohol (UNII: ND2M416302)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-100-04	113 g in 1 JAR; Type 0: Not a Combination Product	01/04/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/23/2012	

Labeler - Southern Sales & Service, Inc. (013114906)**Establishment**

Name	Address	ID/FEI	Business Operations
Southern Sales & Service, Inc.		013114906	LABEL(69822-100)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(69822-100)