

**ICE QUAKE- 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.*

-----

**Ice Quake**

**Drug Facts**

**Active Ingredient**

**Menthol 15%**

**PURPOSE**

Topical analgesic

**Uses**

temporarily relieves minor pain associated with:

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

**Warnings**

**For external use only.**

**When using this product**

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or 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.
- 
- **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.

**MANUFACTURED BY:**

**GADAL Laboratories, Inc. • Miami, FL 33186**

**PRINCIPAL DISPLAY PANEL - 113 g Tube Label**

***ICEQUAKE***

**Pain Relieving GEL**

**Menthol**

**15%**

**Net wt 4 oz (113 g)**



MANUFACTURED BY:  
GADAL Laboratories, Inc. • Miami, FL 33186  
www.gadalaboratories.com

# ICEQUAKE

Pain Relieving GEL **Menthol 15%**

Net wt 4 oz (113 g)

**Drug Facts**

**Active Ingredient:** Menthol 15%.....**PURPOSE:** Topical analgesic

**Uses:** temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains • bruises • cramps  
**Warnings:** For external use only. When using this product • use only as directed • do not bandage tightly or use with a heating pad • avoid contact with eyes or mucous membranes • do not apply to wounds or 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.

• IF MEDICINE COMES IN CONTACT WITH HANDS, WASH WITH SOAP AND WATER

**Inactive Ingredients:** HPMC, Glycerina, FD&C blue #1, Carbopol, Isopropyl alcohol, Propylene glycol, Methylparaben, Sodium hydroxide, Purified water.

menthol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-100
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: H3R47K3TBD)	
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Methylparaben (UNII: A28C7H9T)	
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:53113-100-01	113 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part348	08/23/2012	

**Labeler** - Gadal Laboratories, Inc. (841305639)

### Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Revised: 9/2012

Gadal Laboratories, Inc.