

ICE QUAKE PLUS- methyl salicylate, menthol, camphor 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
Methyl Salicylate 10%	Topical Analgesic
Menthol 10%	Topical Analgesic
Camphor 3.1%	Topical Analgesic

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with

- arthritis
- simple backache
- muscle strains
- bruises
- sprains
- 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 the eyes and 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 reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

- **adults and children over 12 years:**
- apply to affected
- squeeze desired amount of IceQuake Plus onto affected area

- massage dispensed gel into painful area until thoroughly absorbed
- repeat as necessary, but no more than 3 to 4 times daily

☐☐**Inactive ingredients:** HPMC, glycerin, FD&C Blue No.1, carbopol, isopropyl alcohol, propylene glycol, methylparaben, sodium hydroxide, water

SSS Group, LLC Miami, Fl 33183



NDC: 53113-266-04

MANUFACTURED BY: GADAL Laboratories, Inc. Miami, FL 33186 www.gadallaboratories.com
DISTRIBUTED BY: SSS GROUP, LLC. Miami FL 33186

ICEQUAKE

Pain Relieving Gel PLUS

Drug Facts

Net wt 4 oz (113 g)

Active Ingredient:

Purpose:

Menthol 10%.....	Topical analgesic
Methylsalicylate 10%.....	Topical analgesic
Camphor 3.1%.....	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 PLUS 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.

ICEQUAKE PLUS

methyl salicylate, menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-266
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-266-04	113 g in 1 TUBE		

Marketing Information

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

Labeler - Gadal Laboratories Inc (841305639)

Revised: 9/2013

Gadal Laboratories Inc