

ICE QUAKE PLUS- methyl salicylate, menthol, camphor cream
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.

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
- Strains
- Bruises
- Sprains
- Cramps

Warnings

□ For external use only

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

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops

When using this product:

- Use only as directed
- Do not bandage tightly
- Do not use with a heating devices
- Avoid contact with the 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

Keep out of reach of children.

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

Directions

- **adults and children over 18 years and older:**
- Apply to affected area
- Squeeze desired amount of IceQuake Plus onto affected area
- massage dispensed cream 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

DISTRIBUTE BY:

SSS Group, LLC Pembroke Pines, Fl 33332

Questions or Comments?

Call 1 800.213.9370

ICE QUAKE PLUS

LOT#: EXP: NDC# 69822-101-04

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



ICEQUAKE®

Pain Relieving Cream PLUS

Net Wt. 4 oz (113 g)

Drug Facts

Active ingredients

Menthol 10%	Topical Analgesic
Methylsalicylate 10%	Topical Analgesic
Camphor 3.1%	Topical Analgesic

Purpose

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple backache
- Strains
- Sprains
- Bruises

Warnings

For external use only ■ avoid contact with eyes and mucous membranes ■ do not use otherwise than as directed

Caution: Discontinue use if excessive irritation of the skin develops.

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: carbopol, cetearyl alcohol, disodium EDTA, FD&C blue no. 1, glycerin, hydroxypropyl methylcellulose, methylparaben, propylene glycol, polysorbate 20, purified water, stearic acid, sodium hydroxide.

ICEQUAKE PLUS

methyl salicylate, menthol, camphor cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69822-101
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 HOMO POLYMER 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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-101-04	113 g in 1 TUBE; Type 0: Not a Combination Product	01/05/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	01/01/2013	

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

Name	Address	ID/FEI	Business Operations
Southern Sales & Service, Inc.		013114906	LABEL(69822-101)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(69822-101)