

ICE QUAKE ROLL ON- menthol camphor (natural) 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.

Gadaderm Frocen Ice FastmPain Releive

ACTIVE INGREDIENT

Active Ingredients	Purpose
Menthol 3.5%	Topical Analgesic
Camphor 0.2%	Topical Analgesic

INACTIVE INGREDIENT

Carbomer, Propylene Glycol, Methylparaben, Isopropyl Alcohol, Triethanolamine, FD&C Blue #1, Purified Water.

KEEP THIS AND ALL MEDICINE OUT OF REACH OF CHILDREN

In case of accidental ingestion, seek professional help and contact a Poison Control Center immediately.

WARNINGS

For the external use only. Use only as directed.

- Avoid contact with eyes.
- Do not use with other topical products.
- Do not use with heating device.
- Do not apply to open wounds or damaged skin.

Stop Use

- If condition worsens, or if symptoms persist for more than 7 days or clear up and occurs again within a few days, discontinue use of this product and consults a doctor.in.

Uses

For temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains.

DOSAGE & ADMINISTRATION

Adults and children 12 years and older.

- Apply to painful muscles and joints.
- Gently massage thoroughly into affected area.
- Repeat as necessary but no more than 4 times daily

PURPOSE

Topical Analgesic

Other Information:

Store at room temperature with cap closed tightly.

Distribute by:

SSS Group, LLC.

Pembroke Pines, FL 33332

www.icequakeonline.com

Questions or Comments?

1 800.213.9370

Ice Quake Roll On

NDC# 69822-102-03

SHAKE
WELL

Doctors
Recommended

Stain Free
Greaseless



ICEQUAKE[®]
Topical Analgesic Gel **Roll On**

Ice Quake[®]
Advanced Therapy
Pain Relief
can be used for
temporary relief of minor
aches and pains of
muscles associated
with:
**Simple Backache,
Arthritis, Strains,
Bruises and Sprains.**

OPEN HERE

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

3 fl.oz. (89 ml)

Drug Facts

Active Ingredients: Menthol 3.5%
Purpose: Topical analgesic

DRUG FACTS CONTINUED
LIFT LABEL AT TOP RIGHT

LOT#:
EXP.:

Drug Facts Continued

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with: ■ Simple backache ■ Arthritis ■ Strains ■ Bruises ■ Sprains

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 12 years of age and older: apply to affected area not more than 3 to 4 times daily. Children under 12 years of age: consult a doctor.

Other information

- do not freeze - keep lid tightly closed

Inactive ingredients: carbomer, camphor, propylene glycol, methylparaben, isopropyl alcohol, triethanolamine, FD&C blue #1, purified water.

ICEQUAKE ROLL ON

menthol camphor (natural) gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69822-102

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 g in 100 mL
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-102-03	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	01/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	11/01/2016	

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

Name	Address	ID/FEI	Business Operations
Southern Sales & Service, Inc.		013114906	LABEL(69822-102)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(69822-102)

Revised: 1/2017

Southern Sales & Service, Inc.