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 inmediately.

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

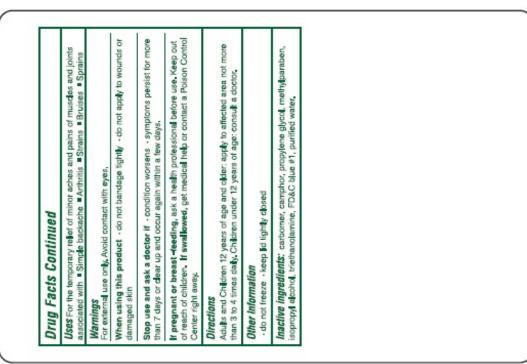
www.icequakeonline.com

Questions or Comments?

1 800.213.9370

Ice Quake Roll On





ICE QUAKE 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: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941)	CAMPHOR (NATURAL)	0.2 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
TROLAMINE (UNII: 903K93S3TK)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
WATER (UNII: 059QF0KO0R)			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:69822-102- 03	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	0 1/0 5/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	11/0 1/20 16	

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.