

ICE QUAKE ANALGESIC CREAM WHITE- methyl salicylate and menthol 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.

ICE QUAKE Analgesic Cream White(Methyl Salicylate and Menthol)

Active Ingredients

Methyl Salicylate 8%

Menthol 2%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- arthritis
- simple backache
- bruises
- strains
- sprains

Warnings

For external use only.

If pregnant or breast-feeding, ask a health professional before use.

When using this product

- use only as directed
- Avoid contact with eyes and mucous membranes
- do not bandage tightly or use with a heating devices
- do not apply to wounds or damaged skin
- Do not apply to irritated skin

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 Immediately.

Directions

Adults and Children 12 Years of Age or Older

- Apply generously to affected area
- Massage into painful area until thoroughly absorbed into skin
- Repeat as necessary, but no more than 3 to 4 times daily

Mineral oil, Propylene glycol, Cetyl stearyl alcohol, Purified water, Cetareth-6, Stearyl alcohol, PEG-20 Cetyl/Stearyl Ether, Methylparaben, propylparaben.

Analgesic Cream White

MENTHOL 2%, METHYL SALICYLATE 8%

NET WT 2 OZ (60 g)

Store: At Room Temperature 15° - 30°C (59° - 86°F). Close cap tightly after use.

EXP: 5
 LOT#: 19192310300
 NDC # 69822-300-02
 icequakeonline.com
 Call 1800.213.9370
 Questions or Comments?
 Pembroke Pines, FL 33332
 Southern Sales Services Inc.
 DISTRIBUTED BY:



Topical Analgesic Cream WHITE

Net Wt. 2 oz (60 g)

Drug Facts	
Active Ingredients	Purpose
Methyl Salicylate 8%.....	Topical Analgesic
Menthol 2%.....	Topical Analgesic
Uses	
For the temporary relief of minor aches and pains of muscles and joints associated with	
<ul style="list-style-type: none"> ■ 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 products ■ 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	
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	
<ul style="list-style-type: none"> ■ store at room temperature 15° - 30°C (59° - 86°F) ■ close cap tightly after use. 	
Inactive Ingredients: mineral oil, propylene glycol, cetyl stearyl alcohol, purified water, ceteareth-6, stearyl alcohol, PEG-20 cetyl/stearyl ether, methylparaben, propylparaben.	

Distribute By: SSS group, LLC
 Pembroke Pines, FL 33332
 Questions or Commnets?
 Call 800.213.9370

ICE QUAKE ANALGESIC CREAM WHITE

methyl salicylate and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69822-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	8.0
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.0

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0K00R)	
CETEARETH-6 (UNII: 2RJS3559D3)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-300-02	1 in 1 TUBE; Type 0: Not a Combination Product	10/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Southern Sales & Service, Inc.		013114906	LABEL(69822-300)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(69822-300)