

**ICE QUAKE WHITE- methyl salicylate, menthol cream**  
**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.*

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<b>Active Ingredients</b>	<b>Purpose</b>
Methyl Salicylate 8%	Topical Analgesic
Menthol 2%	Topical Analgesic

**Purpose**

□ Topical Analgesic

**Uses**

□ For the temporary relief of minor aches and pains of muscles and joints due to

- arthritis
- simple backache
- strains
- bruises
- sprains

**Warnings**

□ **For external use only**

**When using this product:** Use only as directed

- □ avoid contact with the eyes and mucous membranes
- do not bandage tightly
- do not apply to wounds or damaged skin
- do not use with heating devices
- do not apply to irritated skin
- if pregnant or breast feeding, ask a health professional before use

□ **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 2 years of age and older; apply generously to affected area massage into painful area until thoroughly absorbed into skin. Repeat if necessary but not more than 3 to 4 times daily.

□ **Inactive ingredients:** □ mineral oil, propylene glycol, cetyl stearyl alcohol, purified water, cetareth-

6, stearyl alcohol, PEG-20 Cetyl/stearyl ether, methylparaben, propylparaben

SSS Group, LLC Miami, Fl 33183



NDC 53113-688-5

DISTRIBUTED BY:  
SSS GROUP, LLC.  
Miami, FL 33186

MANUFACTURED BY:  
GADAL Laboratories, Inc.  
Miami, FL 33186  
www.gadalaboratories.com

### Drug Facts

#### Active Ingredients

Methyl Salicylate 8%.....	Topical Analgesic
Menthol 2%.....	Topical Analgesic

#### Purpose:

**Uses:** For the temporary relief of minor aches and pains of muscles and joints due to

- Arthritis    ▪ Simple backache    ▪ Bruises    ▪ Sprains    ▪ Strains

#### Warnings    For external use only

**Directions:** Adults and children 12 years of age and older. Apply generously to affected area massage into painful area until thoroughly absorbed into skin. Repeat necessary but not more than 3 to 4 times daily.

**Inactive Ingredients:** Mineral oil, Propylene glycol, Cetyl stearyl alcohol, Purified water, Ceteareth-6, Stearyl alcohol, PEG-20 Cetyl/Stearyl Ether, Methylparaben, propylparaben.

**When Using This Product:** Use only as directed • Avoid contact with eyes and mucous membranes  
Do not apply to wounds or damaged skin • Do not bandage tightly • Do not use with heating devices •  
Do not apply to irritated skin • If pregnant or breast feeding, ask a health professional before use •  
If swallowed, get medical help or contact a Poison Control Center Immediately.

#### Stop use and ask a doctor if:

- Condition worsens • Redness is present • Irritation develops

#### Keep out of reach of children

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



**ICEQUAKE**  
Analgesic Cream White

**Net Wt. 2 oz (60 g)**

# ICE QUAKE WHITE

methyl salicylate, menthol cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53113-688
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	8 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CETEARETH-6 (UNII: 2RJS3559D3)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-688-05	60 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