**ICEQUAKE COLD HOT- menthol patch**
**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.*

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**ICEQUAKE Cold'n Hot**

## WARNINGS

For External Use Only.

## ACTIVE INGREDIENT

Active Ingredient .....Purpose
Menthol 5%.....Topical Analgesic

## INACTIVE INGREDIENT

Aluminium glycinate,1,3-buthylene Glycol, Carboxymethylcellulose Sodium, Concentrated Glycerin, diethylene Glycolmonoethyl Ether, Disodium Edetate, Methyl Parahydroxybenzoate, Polyacrylic Acid Solution, Polysorbate 80, Propyl Parahydroxybenzoate, Purified Water, Sodium Polyacrylate, Tartaric Acid, Titanium Oxide

## INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis<br />■ muscle strains ■ muscle sprains ■ bruises ■ cramps

## DOSAGE & ADMINISTRATION

**Adults and children 12 years of age and over:** Carefully remove backing from patch.

Apply one patch to affected area

Repeat as necessary, but no more than 4 times daily.

Children under 12 years of age: Ask a doctor.

## PURPOSE

Topical Analgesic

## When using this product

Use only as directed

■ Do not bandage tightly.

■ Do not use a heating pad.

■ Avoid contact with eyes and mucous membranes.

■ Don’t apply to wounds or damaged skin.

■ Do not use if you are alergic to any ingredients of this product.

**Stop use and ask a doctor**

■ If condition worsens

■ If symptoms persist for more than 7 days or clear up and occur again within a few days.

■ If redness is present

■ If irritation develops

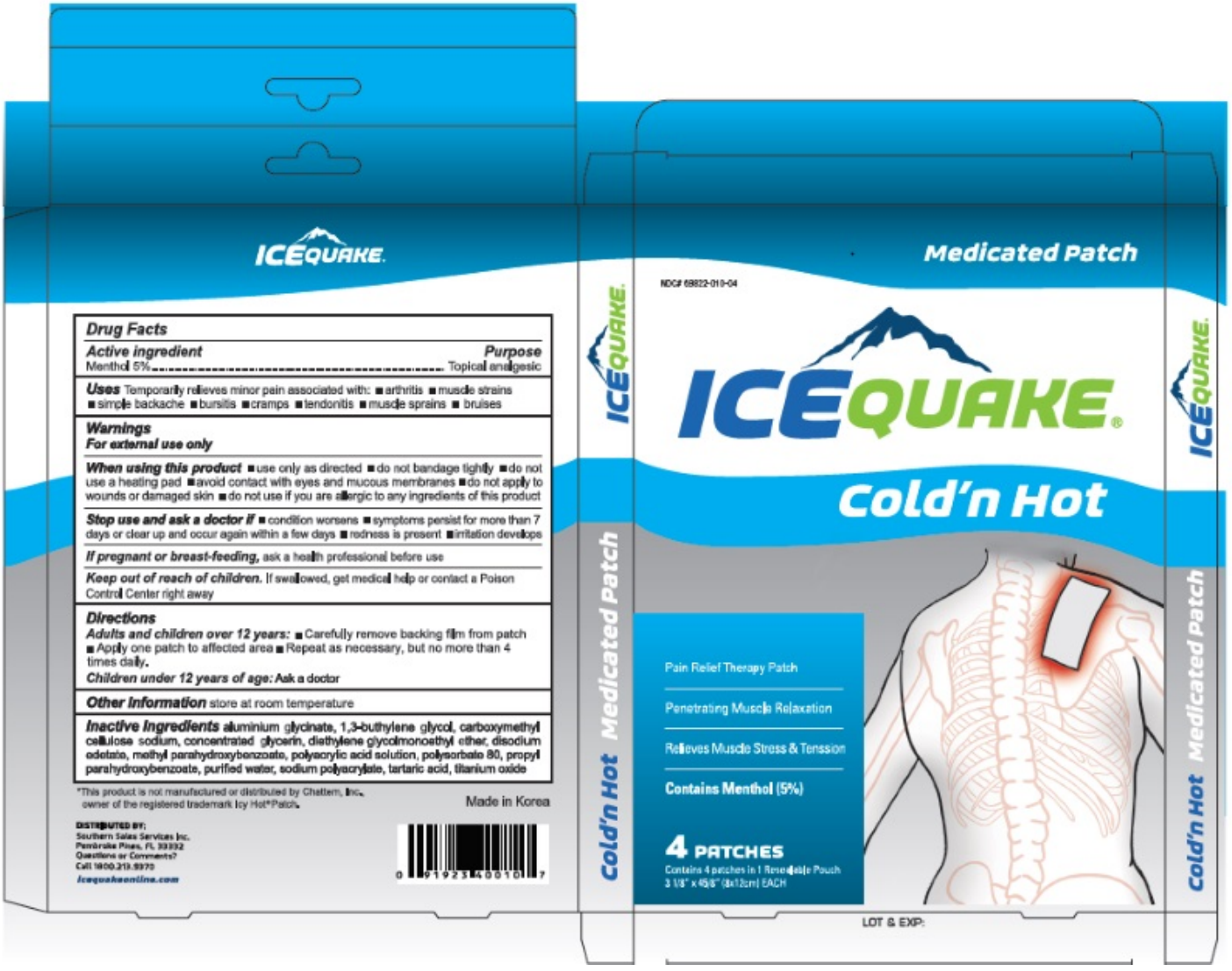
**KEEP OUT OF REACH OF CHILDREN**

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

**If pregnant or breastfeeding**

ask a health professional before use.

Southern Sales Services Inc
Pembroke Pines, FL 33332



# ICEQUAKE COLD HOT

menthol patch

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69822-010 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **DIHYDROXYALUMINUM AMINOACETATE** (UNII: DO250MG0W6) | |
| **BUTYLENE GLYCOL** (UNII: 3XUS85K0RA) | |
| **CARBOXYMETHYLCELLULOSE SODIUM** (UNII: K679OBS311) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **DIETHYLENE GLYCOL** (UNII: 61BR964293) | |
| **EDETATE DISODIUM ANHYDROUS** (UNII: 8NLQ36F6MM) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYACRYLIC ACID (250000 MW)** (UNII: 9G2MAD7J6W) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM POLYACRYLATE (2500000 MW)** (UNII: 05I15JNI2J) | |
| **TARTARIC ACID** (UNII: W4888I119H) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69822-010-04 | 4 in 1 BOX | 03/01/2019 | |
| **1** | | 9 g in 1 PATCH; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 03/01/2019 | |

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

Revised: 3/2019 Southern Sales & Service, Inc.