ICEQUAKE COLDN HOT MEDICATED- 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.

IceQuake Coldn Hot Medicated Patch

Drug Facts

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with:

- arthritis
- muscle strains
- simple backache
- bursitis
- cramps
- tendonitis
- muscle srains
- bruises

Warnings

For external use only

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
- do not apply to wounds or damaged skin
- do not use if you are allergic to any ingredients of this product

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
- redness is present
- irritation develops

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 over 12 years

- Carefully remove backing film from patch
- Apply one patch to affected area
- Use one patch at a time, 1 or 2 times a day

Children under 12 years of age

Consult a physician

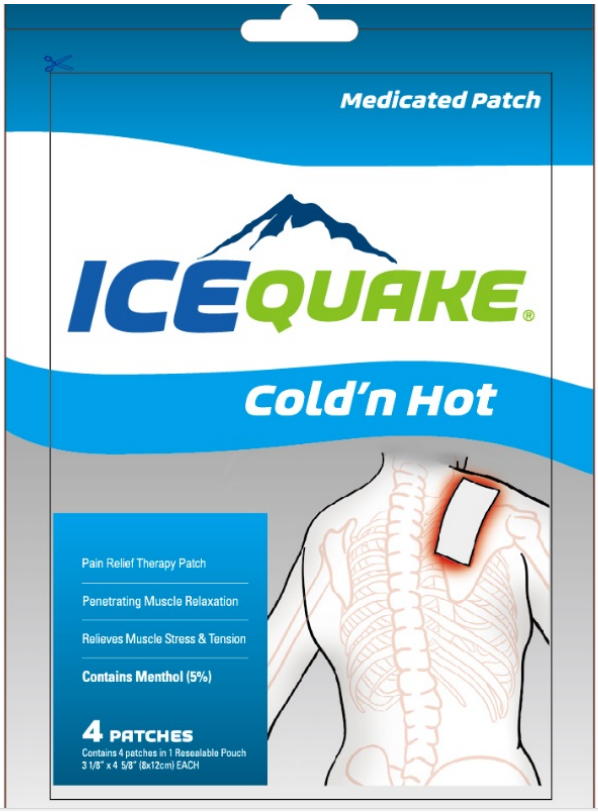
Other information

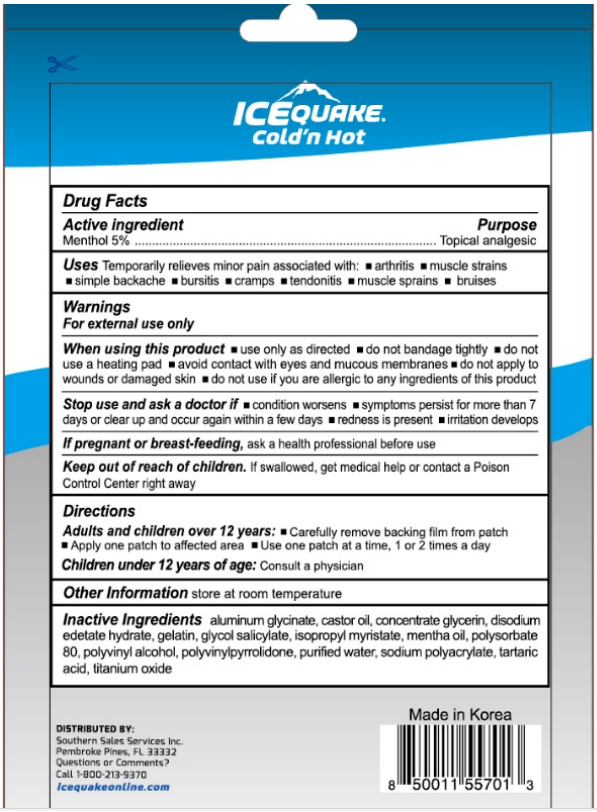
store at room temperature

Inactive Ingredients

aluminum glycinate, castor oil, concentrate glycerin, disodium edetate hydrate, gelatin, glycol salicylate, isopropyl myristate, mentha oil, polysorbate 80, polyvinyl alcohol, polyvinylpyrrolidone, purified water, sodium polyacrylate, tataric acid, titanium oxide

IceQuake Coldn Hot Medicated Patch 69822-010-04





ICEQUAKE COLDN HOT MEDICATED

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69822-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCOL SALICYLATE (UNII: 3I1VBB7AXH)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
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:69822-012-01	4 in 1 PACKAGE	03/01/2019	08/31/2025
1		1 in 1 PACKET		
1		9.5 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2019	08/31/2025

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

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

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