SOUNDBODY COLD AND HOT PAIN RELIEF- menthol patch
Kareway Product, 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.

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 sprains
- 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 membrane
- 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:

- Remove backing from patch by grasping both ends firmly and gently pulling until backing separates in middle
- 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

Other information

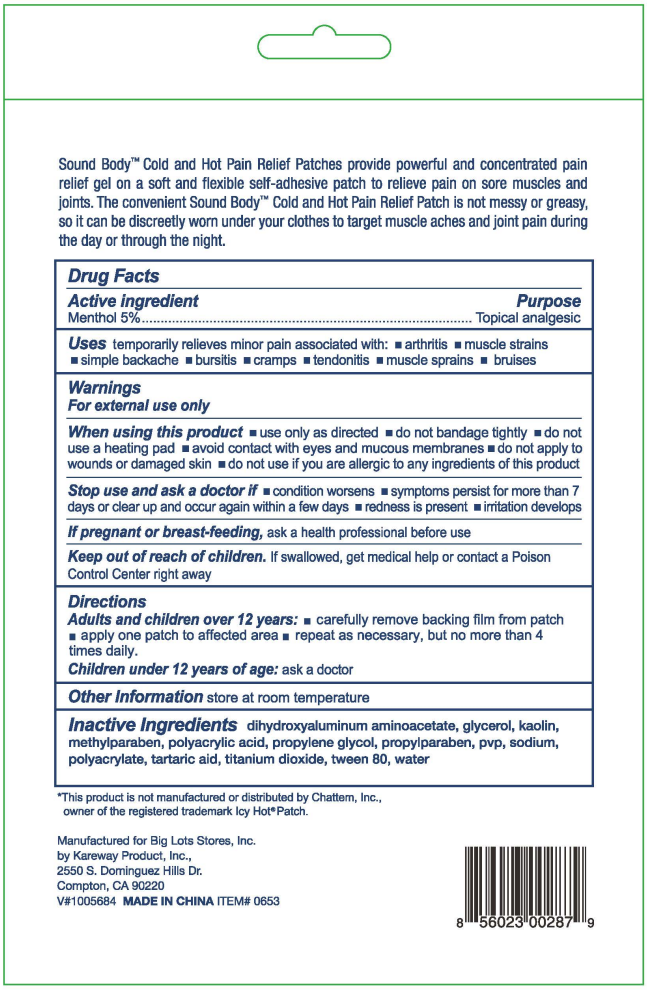
store at room temperature

Inactive ingredients

dihydroxyaluminum aminoacetate, glycerol, kaolin, methylparaben, polyacrylic acid, propylene glycol, propylparaben, pvp, sodium polyacrylate, tartaric acid, titanium dioxide, tween 80, water

package label

Cold and Hot Pain Relief Patch



SOUNDBODY COLD AND HOT PAIN RELIEF

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0287
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	400 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYACRYLIC ACID (8000 MW) (UNII: 7386 1X4K5F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	

KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONES (UNII: FZ989GH94E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0287-2	2 in 1 POUCH; Type 0: Not a Combination Product	05/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/11/2018	

Labeler - Kareway Product, Inc. (121840057)

Revised: 9/2018 Kareway Product, Inc.