MEDICATED 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

L-Menthol 5%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with:
- arthritis
- simple backache
- bursitis
- muscle sprains
- bruises

Warnings

For external use only

When using this product
- use only as directed
- do not bandage tightly or use a heating pad
- avoid contact with eyes and mucous membrane
- 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
- 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
- Repeat as necessary, but no more than 4 times daily.

Children 12 years or younger:

ask a doctor

Other Information

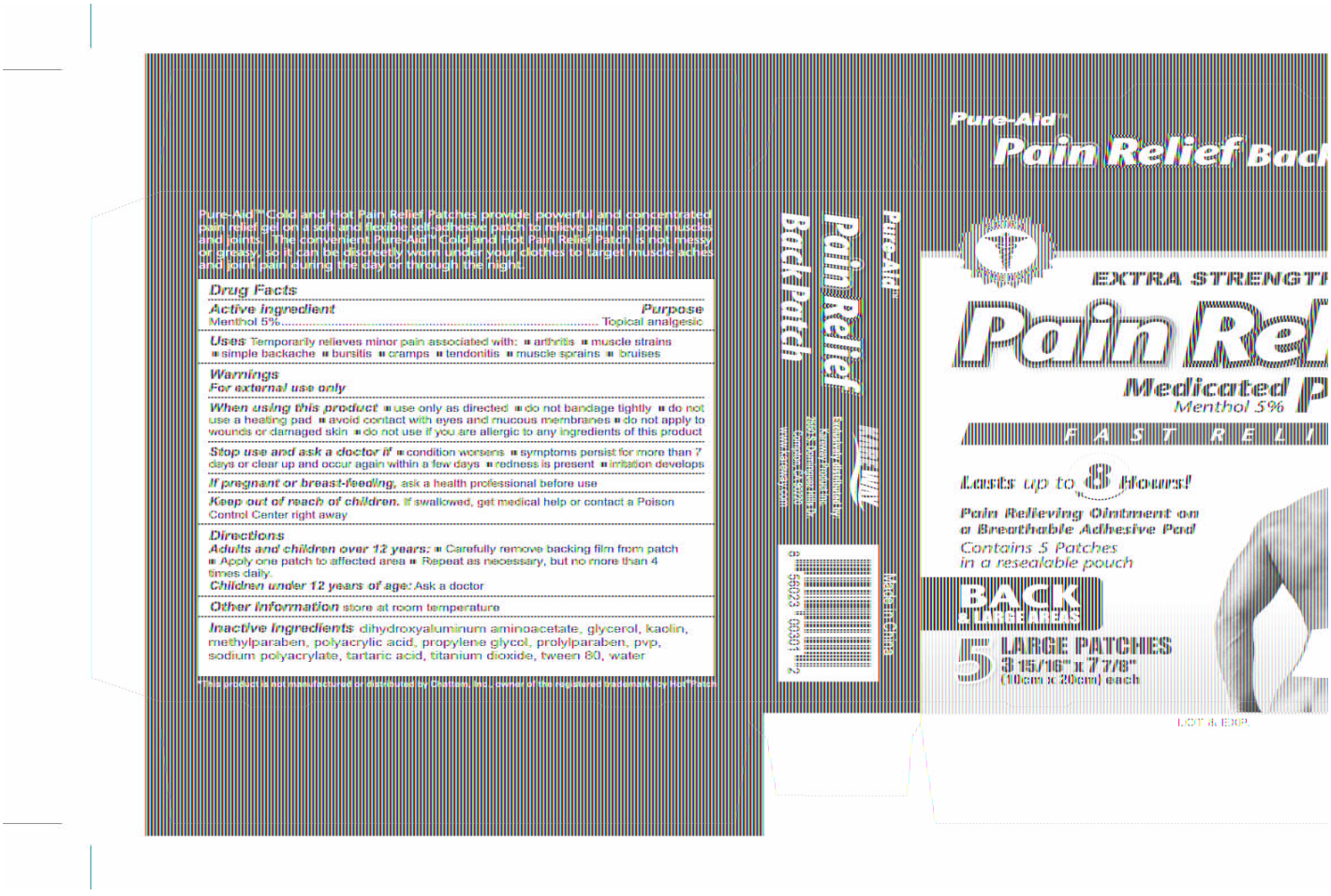
store at room temperature

Inactive ingredients

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

package label

Pain Relief Medicated Patch



MEDICATED PAIN RELIEF

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-1301

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
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
KAOLIN (UNII: 24H4NWX5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-1301-5	1 in 1 CARTON	09/12/2011	
1		5 in 1 POUCH; 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	09/12/2011	

Labeler - Kareway Product, Inc. (121840057)

Establishment

Name	Address	ID/FEI	Business Operations
TDS Pharm Co., Ltd.		694894612	manufacture(67510-1301)

Revised: 3/2019 Kareway Product, Inc.