# MEDICATED PAIN RELIEF HOT- menthol, capsicum extract 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.

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#### **Drug Facts**

## **Active ingredients**

L-Menthol 0.4%

Capsicum Extract (0.002% of Capsaicin)

## **Purposes**

Topical analgesic

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 12 years of age and older: Clean and dry affected area. Remove backing film and apply not more than 3 to 4 times daily.

Children under 12 years of age: Consult a physician.

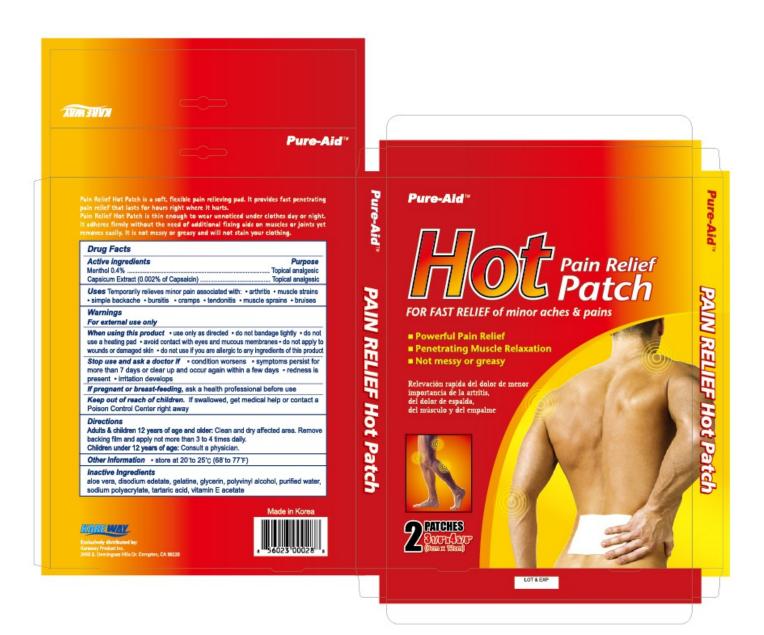
#### Other information

store at 20° to 25°C (68° to 77°F)

# **Inactive ingredients**

Purified water, Glycerin, Disodium edetate, Tartaric acid, Gelatine, Polyvinyl alcohol, Sodium polyacrylate, Vitamin E acetate, Aloe vera

# Package label



#### MEDICATED PAIN RELIEF HOT

menthol, capsicum extract patch

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67510-0226 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHO L	46.92 mg	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg	

Inactive Ingredients	
Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
TARTARIC ACID (UNII: W48881119H)	
GELATIN (UNII: 2G86QN327L)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67510-0226-2	1 in 1 CARTON	09/16/2011		
1		2 in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:67510-0226-4	1 in 1 CARTON	09/16/2011		
2		4 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	09/16/2011			

# **Labeler** - Kareway Product, Inc. (121840057)

Revised: 7/2019 Kareway Product, Inc.