

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.

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)	MENTHOL	46.92 mg
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TARTARIC ACID (UNII: W4888119H)	
GELATIN (UNII: 2G86QN327L)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

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)

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Kareway Product, Inc.