

COLD AND HOT PAIN RELIEF SLEEVE- 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.

Pure-Aid Cold & Hot Sleeve

Active ingredient

Menthol 16%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with arthritis, bursitis, tendonitis, muscle strains, muscle sprains, bruises and cramps.

Warnings

For external use only

When using this product

- use only as directed
- do not bandage tightly or use with 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

- **Clean and dry affected area.**
- **Cut open pouch and remove Sleeve.**
- **Remove the clear plastic insert.**
- **Pull Sleeve onto knee, large ankle or elbow.**
- **Medication is on the colored section of the Sleeve, so the colored section should be placed on**

the affected area.

- Pull Sleeve over itself to make medicine touch directly on your skin.
- Apply one Sleeve to affected area.
- Repeat as necessary , but no more than 4 times a day.
- Sleeve should fit snug, but not tight.

Children 12 years or younger:

- ask a doctor

Inactive ingredients

Glycerin, Hydroxyethylcellulose, Isopropyl Alcohol, Polysorbate 80, Methylparaben, Propylparaben, Purified Water

Package label



COLD AND HOT PAIN RELIEF SLEEVE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0085
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
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0085-4	1 in 1 BOX	04/19/2012	
1		1 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	04/19/2012	

Labeler - Kareway Product, Inc. (121840057)

Revised: 9/2020

Kareway Product, Inc.