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.

Pure-Aid Pain Relief Patch

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 or 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:

Carefully remove backing 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

Inactive ingredients

aluminium glycinate, 1,3-butylene glycol, carboxymethyl cellulose sodium, concentrated glycerin, diethylene glycomonoethyl ether, disodium edetate, methyl parahydroxybenozate, polyacrylic acid solution, polysorbate 90, propyl parahydroxybenzoate, purified water, sodium polyacrylate, tartaric acid, titanium oxide

package label

Pain Relief Medicated Patch



MEDICATED PAIN RELIEF

menthol patch

Product Information	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	428.5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
GLYCERIN (UNII: PDC6A3C0OX)		
1,3-BUTYLENE GLYCOL 1-PROPIONATE (UNII: 17U77WTV66)		
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)		

COBALT DISODIUM EDETATE (UNII: 3EY1Y2QRLI)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510- 0301-5	1 in 1 CARTON	12/01/2011	
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	
111101			

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2023 Kareway Product, Inc.