CAPSAICIN PAIN RELIEF- capsaicin 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 Capsaicin Pain Relief Patch

Active ingredient

Capsicum extract 0.025% as Capsaicin

Purpose

Topical analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only.

Discontinue use at least 1 hour before a bath or shower and do not use immediately after a bath or shower.

Do not use
- on wounds or damaged skin
- with a heating pad
- with, or at the same times as other external analgesic products
- if you are allergic to any ingredients of this product

When using this product
- **use only as directed**
- avoid contact with the eyes, mucous membranes or rashes

Stop use and ask a doctor if
- rash, itching or excessive skin irritation develops
- conditions worsen
- symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

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 over:

- Clean and dry affected area
- Remove patch from film
- Apply to affected area not more than 3 to 4 times daily for 7 days
- Remove patch from the skin after at most 8 hour's application

Children under 12 years of age:
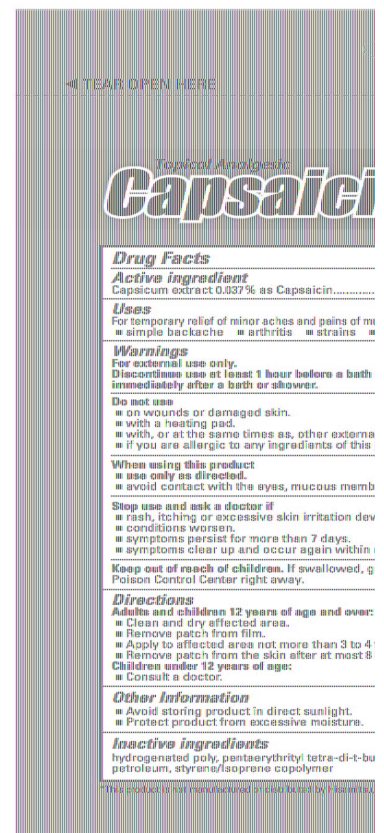
- Consult a doctor

Other information

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive ingredients

hydrogenated poly, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, petroleum, styrene/isoprene copolymer

Package label

Capsaicin Hot Patch

CAPSAICIN PAIN RELIEF
capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.702 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0303-1	1 in 1 CARTON	01/23/2012	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67510-0303-2	2 in 1 POUCH; Type 0: Not a Combination Product	05/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/23/2012	

Labeler - Kareway Product, Inc. (121840057)

Revised: 6/2018

Kareway Product, Inc.