

CAPSAICIN HEAT- capsaicin patch
Universal Distribution Center LLC

Capsaicin Heat Patch

Drug Facts

Active Ingredient

Capsicum Extract Capsaicin 0.025%

Purpose

Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles & joints associated with:

- Simple Backache
- Arthritis
- Strains
- Bruises
- Sprains

WARNINGS:

EXTERNAL USE ONLY

DO NOT USE

- on wounds or damaged skin
- with a heating pad
- with or at the same times as other external analgesic
- if you are allergic to any ingredients of this product

When using this product

- do not use otherwise than as directed.
- avoid contact with the eyes, mucous membranes or rashes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

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 few days

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 (1-800-222-1222)

immediately.

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
- Remove patch from skin after at most 8 hours of 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

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Propylene Glycol, Polysorbate 80, Carboxymethylcellulose Sodium, Carbomer, Purified Water, POVIDONE K90, Tartaric Acid, DMDM Hydantoin

Compare to the active ingredient in Salonpas® - Hot Capsicum Patch®

*This product is NOT manufactured or distributed by Hisamitsu®, owner of Salonpas® Hot Capsicum Patch.

Distributed by:

Universal Distribution Center

96 Distribution Boulevard • Edison, NJ 08817

Made in P.R.C.

Packaging



**Arthritis
Backaches
Bruises
Sprains**

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ITEM#82632
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Made in P.R.C.

DRUG FACTS LABEL

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CAPSAICIN HEAT

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)		CAPSAICIN	0.025 g in 100 g	
Inactive Ingredients				
Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C00X)				
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)				
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
KAOLIN (UNII: 24H4NWX5CO)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)				
WATER (UNII: 059QF0K00R)				
POVIDONE K90 (UNII: RDH86HJV5Z)				
TARTARIC ACID (UNII: W4888I119H)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-040-41	1 in 1 BOX	03/07/2019	
1	NDC:52000-040-40	2 in 1 POUCH		
1		3.28 g in 1 PATCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017		03/07/2019	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Universal Distribution Center LLC (019180459)

Establishment

Name	Address	ID/FEI	Business Operations
Koolcare Technology Co., Ltd.		602479389	manufacture(52000-040)

