

CAPSAICIN HEAT- capsaicin patch
Universal Distribution Center LLC

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.

Capsaicin Heat Patch

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 a 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

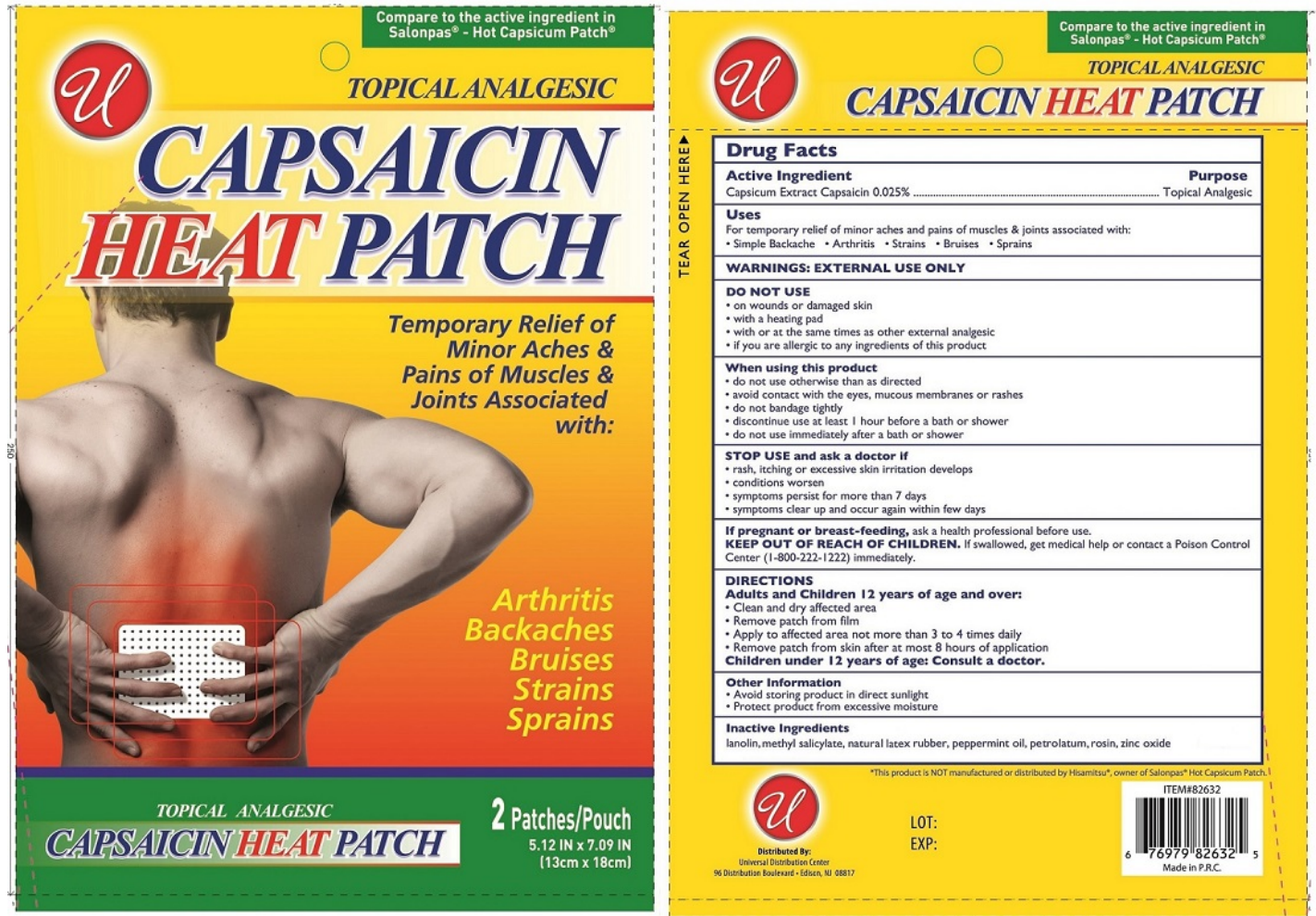
- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Inactive Ingredients

lanolin, methyl salicylate, natural latex rubber, peppermint oil, petrolatum, rosin, zinc oxide

PRINCIPAL DISPLAY PANEL

Capsaicin Heat Patch



| 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 |
|---|----------|
| LANOLIN (UNII: 7EV65EAW6H) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| ROSIN (UNII: 88S87KL877) | |
| ZINC OXIDE (UNII: SOI2LOH54Z) | |

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 not final | part348 | 03/07/2019 | |

Labeler - Universal Distribution Center LLC (019180459)**Registrant** - Universal Distribution Center LLC (019180459)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Zhejiang Dingtai Pharmaceutical Co., Ltd | | 420598724 | manufacture(52000-040) |

Revised: 3/2019

Universal Distribution Center LLC