

WELLPATCH WARMING PAIN RELIEF- capsaicin patch

The Mentholatum Company

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.

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

Capsaicin - Topical analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only

- use only as directed
- do not use at least 1 hours before, or immediately after, a bath or shower
- avoid contact with eyes and mucous membranes
- do not apply to wounds or to damaged or very sensitive skin
- do not bandage tightly or use with a heating pad

Stop use and ask a doctor if

- condition worsens
- excessive redness, irritation, burning or discomfort of the skin develops
- symptoms persist for more than 7 days or 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 and over: apply to affected area; change patch 1 to 2

times daily

- children under 12 years: ask a doctor
- FOR BEST RESULTS: apply to clean, dry skin
- tear open pouch and remove patch; if desired, cut patch to size
- grasp both ends of the patch firmly with thumbs near center
- stretch patch until the backing separates
- remove protective film while applying patch directly to site of pain
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

Inactive ingredients

carboxymethylcellulose sodium, castor oil, dihydroxyaluminum aminoacetate, edetate disodium, glycerin, methylparaben, partially neutralized polyacrylate, polyacrylic acid, polysorbate 80, polyvinyl alcohol, propylene glycol monocaprylate, purified water, sodium polyacrylate, sodium polyacrylate starch, sorbitol solution, talc, tartaric acid

Questions or comments?

Toll free **1-877-636-2677** MON-FRI 9 AM to 5 PM (EST)

Package/Label Principal Display Panel

WellPatch®

WARMING PAIN RELIEF PATCH

NATURAL  CAPSAICIN

- Arthritis & Joint Pain
- Nerve Pain
- Sore Muscles
- Backache

Odor Free
Comfortable Adhesion

**1 EXTRA LARGE
PATCH**
8" x 4" (20 x 10 cm)



Principal Display Panel

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■ simple backache ■ arthritis ■ strains ■ sprains

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www.wellpatch.com

HOW TO APPLY!

EASY PEEL FILM!

1. Grasp both ends of patch firmly, with thumbs near center.



2. Stretch patch until the backing separates.



3. Apply exposed portion of the



Distributed by/Consignor:
The Mentholatum Company
707 Searing Drive,
Orchard Park,
NY 14127 USA
Manufactured by/Consignor:
Mentholatum (China)
Pharmaceuticals
Co., Ltd.
The Second Industrial
Estates, Sandang,
Zhongshan,
Guandong, China
Made in China

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ZA314003



Batch No
Range

WELLPATCH WARMING PAIN RELIEF

capsaicin patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10742-8127 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | |
| CASTOR OIL (UNII: D5340Y2I9G) | |
| DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| PROPYLENE GLYCOL CAPRYLATE (UNII: RT9P9S09QI) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L) | |
| SORBITOL (UNII: 506T60A25R) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TARTARIC ACID (UNII: W4888I119H) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10742-8127-1 | 1 in 1 POUCH; Type 0: Not a Combination Product | 12/05/2016 | |
| 2 | NDC:10742-8127-2 | 4 in 1 POUCH; Type 0: Not a Combination Product | 12/05/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 12/05/2016 | |

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| The Mentholatum Company | | 002105757 | label(10742-8127) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|-------------------------|
| Mentholatum China Pharmaceuticals Co. Ltd. | | 420786030 | manufacture(10742-8127) |

Revised: 2/2023

The Mentholatum Company