

RELEEVIA MC- menthol and capsaicin patch

Patchwerx Labs, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

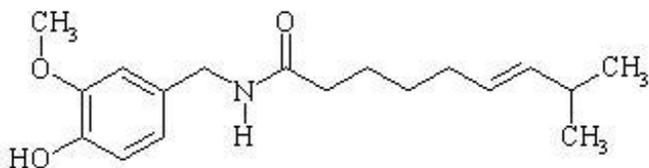
Releevia MC Patch

DESCRIPTION

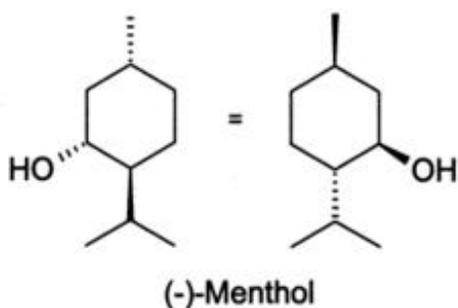
Releevia MC Patch contains capsaicin and menthol in a localized dermal delivery system. The capsaicin in Releevia MC is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is soluble in alcohol, acetone, and ethyl acetate and very slightly soluble in water. The menthol is slightly soluble in water.

Releevia MC is a single-use patch stored in a foil pouch. Each Releevia MC patch is 8.3 cm x 12.5 cm (104 cm²) and consists of a polyester backing film coated with a drug-containing silicone adhesive mixture, and covered with a removable polyester release liner.

The empirical formula for capsaicin is C₁₈H₂₇NO₃, with a molecular weight of 305.42. The chemical compound capsaicin [(E)-8-methyl-N-vanillyl-6-nonenamide] is an activating ligand for transient receptor potential vanilloid 1 receptor (TRPV1) and it has the following structure:



The empirical formula for menthol is C₁₀H₂₀O, with a molecular weight of 156.27. The chemical compound menthol [(1R,2S,5R)-2-isopropyl-5-methylcyclohexanol] is an activating ligand for transient receptor potential cation channel subfamily M member 8 (TRPM8). It has the following structure:



Each Releevia MC Patch contains 0.0375% capsaicin (0.0375 grams of capsaicin per patch) and 5.00% menthol (5 grams of menthol per patch). The Releevia MC patch contains the following inactive ingredients: Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, EDTA Disodium Salt, Glycerin, Iodopronyl Butylcabamate, Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, and Water.

INDICATIONS AND USAGE

Releevia MC Patch is indicated for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Releevia MC Patch is an external analgesic/counterirritant.

CONTRAINDICATIONS

Releevia MC Patch is contraindicated for those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS

- For external use only.
- Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Do not cover with bandage.
- Do not use on wounds or damaged skin.
- Consult physician for children under 12.
- Do not use if you are allergic to Menthol.
- Stop use and ask a doctor if conditions worsen, symptoms persist for more than 7 days or clear up and occur again within a few days or rash, itching or excessive skin irritation occurs.
- KEEP OUT OF REACH OF CHILDREN.

DOSAGE AND ADMINISTRATION

Releevia MC patch contains 0.0375% capsaicin and 5.00% menthol.

Instructions for Use

- Clean and dry affected area
- Cut open pouch and remove patch
- Remove protective film and apply directly to area of pain
- Apply to affected area not more than 3 times daily
- Wash hands with soap after applying patch
- Reseal pouch containing unused patches

Directions

| | |
|---------------------------------------|--|
| Adults and children 12 years and over | <ul style="list-style-type: none">• apply to affected area• change patch 1 to 2 times daily |
| Children under 12 years | <ul style="list-style-type: none">• consult physician before use |

HOW SUPPLIED

Releevia MC Patch is supplied in cartons with either 1 re-sealable pouch containing 5 patches or 3 re-sealable pouches each containing 5 patches each.

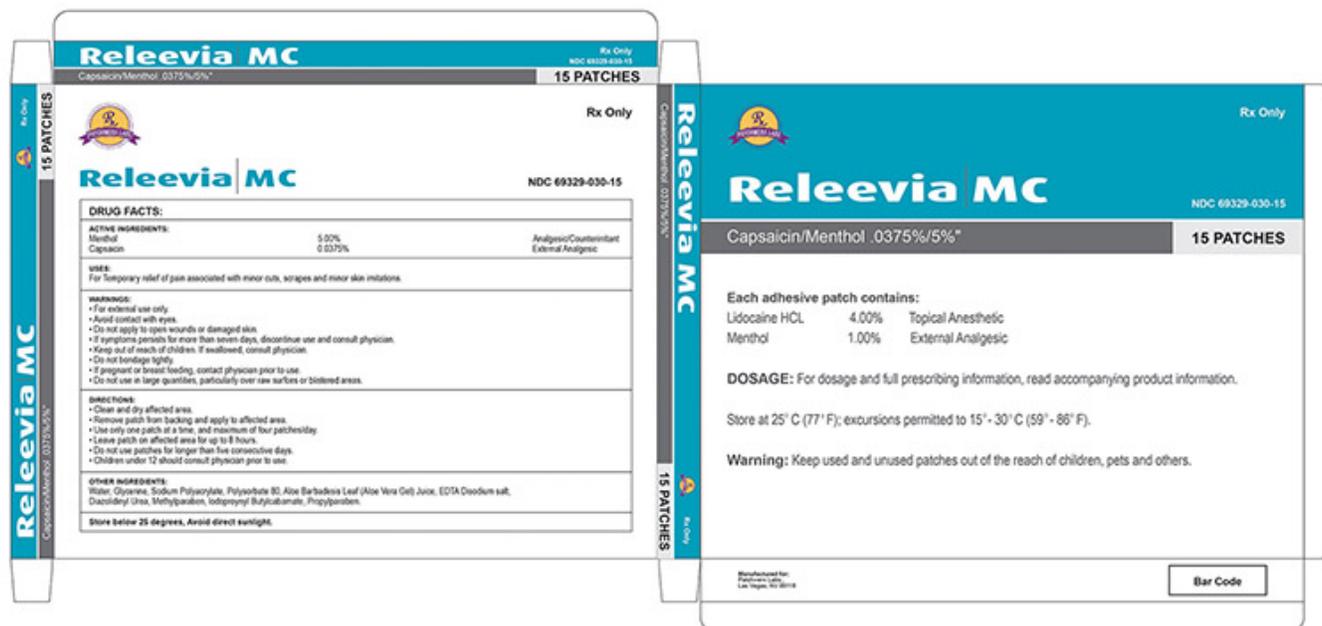
NDC 69329-030-05 5 Patches per carton

NDC 69329-030-15 15 Patches per carton

Storage: Store below 25°C. Avoid direct sunlight.

Manufactured for
Patchwerx Labs, Inc.
Las Vegas, NV 89118
800-590-8070

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



RELEEVIA MC

menthol and capsaicin patch

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|--------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:69 329-030(NDC:69 176-025) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g in 100 g |
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | .0375 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:69329-030-15 | 15 in 1 CARTON | | |
| 1 | | 100 g in 1 PATCH | | |
| 2 | NDC:69329-030-05 | 5 in 1 CARTON | | |
| 2 | | 100 g in 1 PATCH | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 11/17/2014 | |

Labeler - Patchwerx Labs, Inc (079584480)

Revised: 3/2015

Patchwerx Labs, Inc