

RELEEVIA- 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.

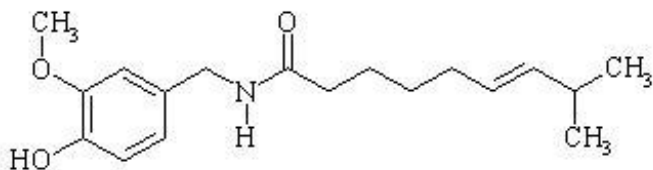
Relevia Patch

DESCRIPTION

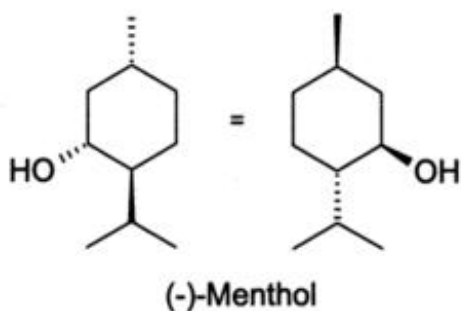
Relevia Patch contains capsaicin and menthol in a localized dermal delivery system. The capsaicin in Relevia is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is soluble in alcohol, acetone, and ethyl acetate and very slightly soluble in water. The menthol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

Relevia is a single-use patch stored in a foil pouch. Each Relevia 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 Relevia Patch contains 0.0375% capsaicin (0.0375 grams of capsaicin per patch) and 5.00% menthol (5 grams of menthol per patch). The Relevia patch contains the following inactive ingredients: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, EDTA Disodium Salt, Glycerin, Iodopropynyl Butylcabamate, Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, and Water.

INDICATIONS AND USAGE

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

Releevia Patch is an external analgesic/counterirritant.

CONTRAINDICATIONS

Releevia 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 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 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 69329-025-05 5 Patches per carton

NDC 69329-025-15 15 Patches per carton

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

Manufactured for

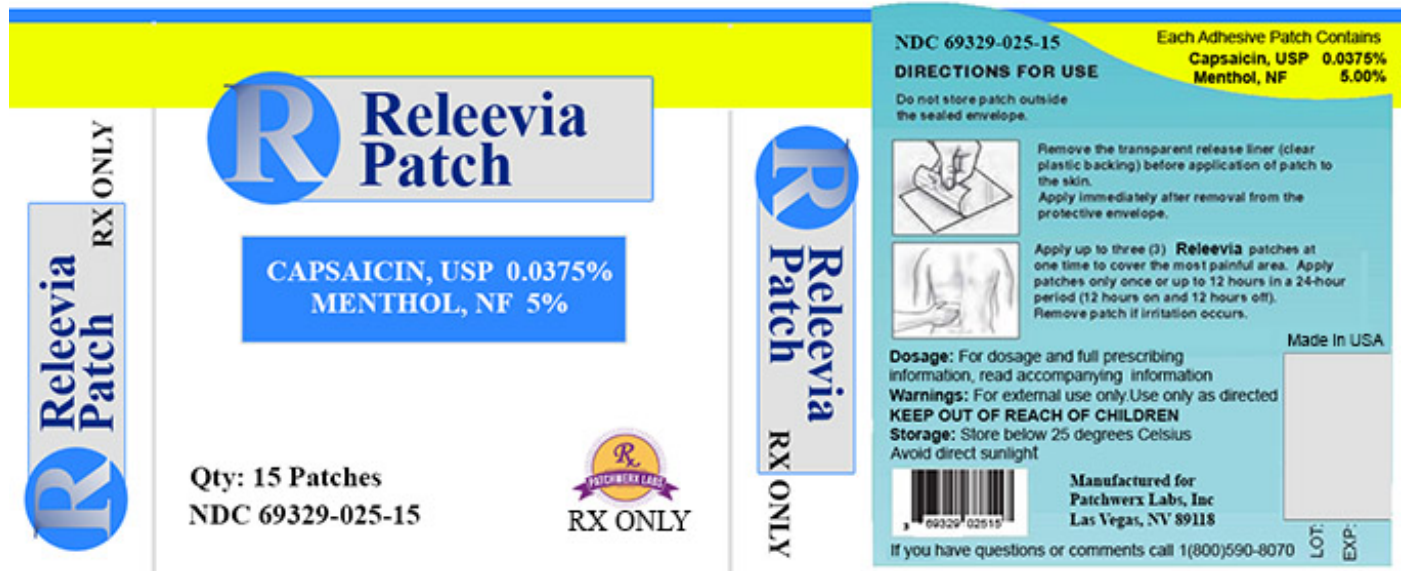
Patchwerx Labs, Inc.

Las Vegas, NV 89118

800-590-8070

Made in USA

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



RELEEVIA

menthol and capsaicin patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69329-025(NDC:69176-025)
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)

WATER (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69329-025-15	15 in 1 CARTON		
1		100 g in 1 PATCH		
2	NDC:69329-025-05	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: 11/2014

Patchwerx Labs, Inc