

## RENOVO - menthol and capsaicin patch TMIG, 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](#).*

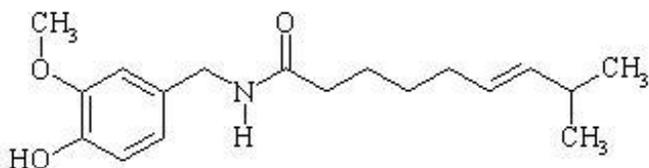
### Renovo Patch

#### DESCRIPTION

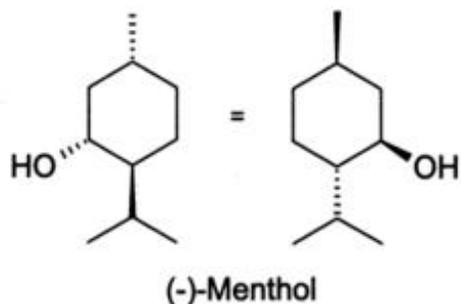
Renovo Patch contains capsaicin and menthol in a localized dermal delivery system. The capsaicin in Renovo is a synthetic equivalent of the naturally occurring compound found in chili peppers. Capsaicin is soluble in alcohol, acetone, and ethyl acetate and very slightly soluble in water. The menthol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

Renovo is a single-use patch stored in a foil pouch. Each Renovo patch is 8.3 cm x 12.5 cm (104 cm<sup>2</sup>) 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 C<sub>18</sub>H<sub>27</sub>NO<sub>3</sub>, 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 C<sub>10</sub>H<sub>20</sub>O, 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 Relovo Patch contains 0.0375% capsaicin (0.0375 grams of capsaicin per patch) and 5.00% menthol (5 grams of menthol per patch). The Renovo patch contains the following inactive ingredients: Aloe Barbadosis Leaf (Aloe Vera Gel) Juice, Diazolidinyl Urea, EDTA Disodium Salt, Glycerin, Iodopropnyl Butylcabamate, Methylparaben, Polysorbate 80, Propylparaben, Sodium Polyacrylate, and Water.

## INDICATIONS AND USAGE

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

Renovo Patch is an external analgesic/counterirritant.

## CONTRAINDICATIONS

Renovo 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

Renovo 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"><li>• apply to affected area</li><li>• change patch 1 to 2 times daily</li></ul>
Children under 12 years	<ul style="list-style-type: none"><li>• consult physician before use</li></ul>

## HOW SUPPLIED

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

NDC 69176-025-03 3 Patches per carton

NDC 69176-025-15 15 Patches per carton

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

Distributed by:  
 TMIG, Inc., Marietta, GA 30062  
 770-579-8883

Manufactured by:  
 Pocono Coated Products, LLC  
 Greensboro, N.C. USA 27407

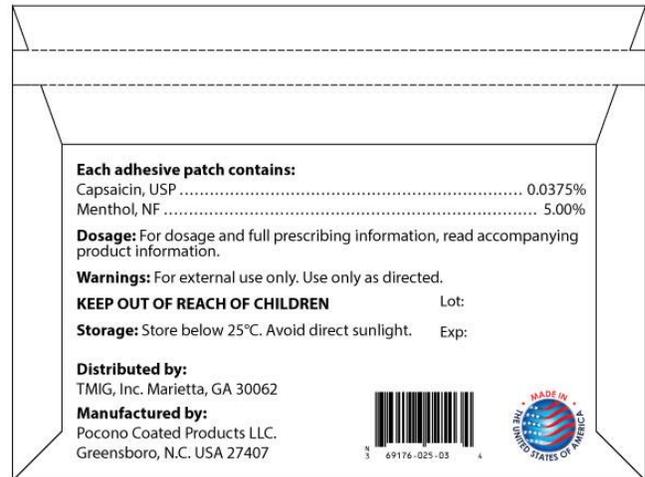
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Size: 8"x 6"

Front



Back



**RENOVO**

menthol and capsaicin patch

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69 176-025
<b>Route of Administration</b>	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	0.0375 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

<b>METHYL PARABEN</b> (UNII: A2I8C7H9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69176-025-15	15 in 1 CARTON		
1		100 g in 1 PATCH		
2	NDC:69176-025-03	3 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		09/25/2014	

**Labeler** - TMIG, Inc. (036572986)

**Registrant** - TMIG, Inc. (036572986)

Revised: 1/2015

TMIG, Inc.