

**MEDI-DERM RX- methyl salicylate, menthol and capsaicin cream**

**Two Hip Consulting, LLC**

*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](#).*

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Active ingredients

Capsaicin 0.035%

Menthol 5%

Methyl Salicylate 20%

**PURPOSE**

**TOPICAL ANALGESIC**

**USES: FOR THE TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH ARTHRITIS, SIMPLE BACKACHE, STRAINS, SPRAINS, MUSCLE SORENESS AND STIFFNESS.**

Warnings: For external use only.

- Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Do not use with heating devices or pads.
- Do not cover or bandage tightly.
- If swallowed, call poison control.
- If contact does occur with eyes rinse with cold water and call a doctor.

**DO NOT USE: ON WOUNDS OR DAMAGED SKIN. CHILDREN UNDER 12 YEARS OLD, CONSULT A DOCTOR. IF YOU ARE ALLERGIC TO ANY INGREDIENTS IN THIS PRODUCT.**

Directions: Use only as directed. Prior to first use, test skin sensitivity by applying a small amount. Apply and massage directly to affected area. Do not use more than 4 times a day. Thoroughly wash hands after application.

Inactive Ingredients: Carbomer, Cetearyl Alcohol, Cypress Oil, Glyceryl Stearate, Green 3 (CI# 42053), Hypromellose, Isopropyl Palmitate, Methylisothiazolinone, Phenoxyethanol, Polysorbate-60, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Water.

**OTHER INFORMATION: STORE BELOW 90°F/32°C**

**QUESTIONS? 888 907-2833**

**IF CONDITION WORSENS, OR IF SYMPTOMS PERSIST FOR MORE THAN 7 DAYS OR CLEAR UP AND OCCUR AGAIN WITHIN A FEW DAYS, DISCONTINUE USE OF THIS PRODUCT AND CONSULT A DOCTOR.**

**IF PREGNANT OR NURSING ASK A HEALTH PROFESSIONAL BEFORE USE.**

**KEEP OUT OF REACH OF CHILDREN.**

# MEDI-DERM<sup>TM</sup>-RX

120ml (4 fl oz) TOPICAL PAIN RELIEF CREAM

## Drug Facts

### Active ingredients

Capsaicin 0.035%.....Topical Analgesic  
Menthol 5%.....Topical Analgesic  
Methyl Salicylate 20%.....Topical Analgesic

### Purpose

**Uses:** For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness.

### Warnings:

**For external use only.**

- Use only as directed • Avoid contact with eyes and mucous membranes • Do not use with heating devices or pads • Do not bandage tightly • If swallowed, call poison control • If contact does occur with eyes, rinse with cold water and call a doctor.
- **Do not use:** On wounds or damaged skin. Children under 12 years old, consult a doctor. If you are allergic to any ingredients in this product.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

**If pregnant or nursing** ask a health professional before use.  
**Keep out of the reach of children.**

**Directions:** Use only as directed. Prior to first use, test skin sensitivity by applying a small amount. Apply and massage directly to affected area. Do not use more than 4 times a day. Thoroughly wash hands after application.

**Other information:** Store below 90°F/32°C

**Inactive ingredients:** Carbomer, Cetearyl Alcohol, Cypress Oil, Glyceryl Stearate, Green 3(CI#42053), Hypromellose, Isopropyl Palmitate, Methylisothiazolinone, Phenoxyethanol, Polysorbate-60, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Water.

Questions? 888 907-2833

Manufactured for [Medi-Sulting.com](http://Medi-Sulting.com)  
547 Cityscape Place San Jose, CA 95136  
Made in the U.S.A [www.medi-derm.net](http://www.medi-derm.net)  
NDC 76074 151 14

## MEDI-DERM RX

methyl salicylate, menthol and capsaicin cream

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG LABEL	<b>Item Code (Source)</b>	NDC:76074-151
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (SALICYLIC ACID)	METHYL SALICYLATE	20 g in 100 mL
MENTHOL (MENTHOL)	MENTHOL	5 g in 100 mL
CAPSAICIN (CAPSAICIN)	CAPSAICIN	0.035 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934	
CETOSTEARYL ALCOHOL	
CYPERUS ESCULENTUS LEAF	
GLYCERYL MONOSTEARATE	
FD&C GREEN NO. 3	
HYPROMELLOSE 2208 (100000 MPAS)	
ISOPROPYL PALMITATE	
METHYLISOTHIAZOLINONE	
PHENOXYETHANOL	
POLYSORBATE 60	
PROPYLENE GLYCOL	
SODIUM HYDROXIDE	
STEARYL ALCOHOL	
WATER	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76074-151-14	120 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/18/2012	

**Labeler** - Two Hip Consulting, LLC (965352896)

**Registrant** - Two Hip Consulting, LLC (965352896)

Revised: 9/2013

Two Hip Consulting, LLC