

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](#).

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-TMDERM-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

547 Cityscape Place San Jose, CA 95136

Made in the U.S.A www.medi-derm.net

NDC 76074 151 14

MEDI-DERM RX

methyl salicylate, menthol and capsaicin cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76074-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	20 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.035 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WT9208)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYPERUS ESCULENTUS LEAF (UNII: T1004HC0OF)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
HYPROMELLOSE 2208 (10000 MPAS) (UNII: VM7F0B23Z1)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC321)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0K00R)	

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