

## **TOPICAL PAIN RELIEF- methyl salicylate, menthol, capsaicin cream**

**Two Hip Consulting, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **ACTIVE INGREDIENTS**

Methyl salicylate 20% (16gm)

Menthol 5% (4 gm)

Capsaicin 0.035% (0.3gm)

### **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. This product does not cure any diseases.

### **WARNINGS**

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.

Discontinue use and consult a physician if condition worsens or irritation develops. Pain persists for more than 7 days. If pain clears up and then redevelops.

Do not use: on cuts or infected skin, on children less than 12 years old, in combination with other topical pain products, if allergic to any ingredients, PABA, aspirin products, or sulfa. Do not use if you are pregnant or nursing. Store below 90 degrees F/32 degrees C. See USP Controlled Temperature.

**KEEP OUT OF 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.

### **Inactive Ingredients**

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

AP

7.0 mm

# MEDI - DERM

120gm (4 fl oz) TOPICAL PAIN RELIEF CREAM

FRONT  
PANEL  
C/L

## Drug Facts

### Active ingredients

### Purpose

Methyl Salicylate 20%.(16gm).....Topical Analgesic  
Menthol 5%.(4gm).....Topical Analgesic  
Capsaicin 0.035%.(0.3gm).....Topical Analgesic

**Use:** For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, muscle soreness and stiffness. This product does not cure any diseases.

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**Keep out of the reach of children.**

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### Discontinue use and consult a physician if:

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**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(Cl#42053), Hypromellose, Isopropyl Palmitate, Methylisothiazolinone, Phenoxyethanol, Polysorbate-60, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Water.

Manufactured for **Two Hip Consulting & Sales. LLC**  
1844 Massachusetts Ave. Riverside, CA 92507  
**Made in the U.S.A** [www.medi-derm.net](http://www.medi-derm.net)  
**NDC CODE 76074 120 01**

BACK  
PAIN

## TOPICAL PAIN RELIEF

menthyl salicylate, menthol, capsaicin cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76074-120
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 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.0355 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
HYPROMELLOSE 2208 (100000 MPAS) (UNII: VM7F0B23Z1)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
WATER (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76074-120-01	120 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2011	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2011	

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