

**MEDI-SULTING TOPICAL PAIN RELIEF- methyl salicylate menthol capsaicin  
lidocaine 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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CAPSAICIN 0.035%

LIDOCAINE 2%

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, Cetaryl 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-DERMAL™

WITH LIDOCAINE

TOPICAL PAIN RELIEF CREAM

120ml (4 fl oz)

## Drug Facts

### Active ingredients

Capsaicin 0.035%.....	Topical Analgesic
Lidocaine 2%.....	Topical Anesthetic
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 Two Hip Consulting /Medi-Sulting.com  
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Made in the U.S.A www.medi-derm.net

**NDC 76074 122 14**

## MEDI-SULTING TOPICAL PAIN RELIEF

methyl salicylate menthol capsaicin lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76074-122
<b>Route of Administration</b>	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

<b>CAPSAICIN</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.0355 g in 100 mL
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>HYPROMELLOSE 2208 (100000 MPA.S)</b> (UNII: VM7F0B23ZD)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76074-122-14	120 mL in 1 TUBE; Type 0: Not a Combination Product	08/18/2012	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/18/2012	

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

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