MEDI-DERM / L WITH LIDOCAINE RX- methyl salicylate menthol capsaicin lidocaine 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.

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.

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.

WARNNGS:

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 TIGHTLYIF 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.



Drug Facts

Active ingredients	Purpose
Capsaicin 0.035%	Topical Analgesic
Lidocaine 2%	Topical Anesthetic
Menthol 5%	The state of the s
Methyl Salicylate 20%	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 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(Cl#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 547 Cityscape Place San Jose, CA 95136 Made in the U.S.A www.medi-derm.net

NDC 76074 152 14

MEDI-DERM / L WITH LIDOCAINE RX

methyl salicylate menthol capsaicin lidocaine cream

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item	em Code (Source) NDC:76074-152
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Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A) MENTHOL CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) CAPSAICIN (DASSAICIN - UNII:S07O44R1ZM) CAPSAICIN (DASSAICIN - UNII:S07O44R1ZM) CAPSAICIN (DASSAICIN - UNII:S07O44R1ZM)

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CYPERUS ESCULENTUS LEAF (UNII: T1004HC0OF)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)		
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3 M)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
STEARYL ALCOHOL (UNII: 2KR8914H1Y)		
WATER (UNII: 059QF0KO0R)		

ı	Pack	Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 ND	C:76074-152-14	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	
unapproved drug other		08/18/2012		

Labeler - Two Hip Consulting, LLC (965352896)

Registrant - Two Hip Consulting, LLC (965352896)

Revised: 2/2019 Two Hip Consulting, LLC