

MEDI-SULTING TOPICAL PAIN RELIEF- methyl salicylate menthol capsaicin lidocaine patch
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.

CAPSAICIN 0.035%

LIDOCAINE 0.5%

MENTHOL 5%

METHYL SALICYLATE 20%

PURPOSE

TOPICAL ANALGESIC

TOPICAL ANESTHETIC

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.

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: ACRLIC ACID, ALUMINUM HYDROXIDE, CARMELLOSE SODIEM, 2-ETHYLHEXYL ACRYLATE, GLYCERIN, ISOPROPYL MYRISTATE, METHYL ACRYLATE, NONOXYNOL-30, POLYACRYLATE, POLYACRYLIC ACID, POLYSORBATE 80, SORBITAN SESQUIOLEATE, STARCH, TALC, TARTARIC ACID, TITANIUM DIOXIDE, 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.

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.

MEDI-PATCH

WITH LIDOCAINE 0.5%

Drug Facts

Active ingredients

Capsaicin 0.035%.....	Topical Analgesic
Lidocaine 0.5%.....	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 use, clean & dry affected area. Remove protective film & apply directly to affected area. Do not use more than 3 times a day. Thoroughly wash hands after application. Reseal pouch after opening.

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

Inactive ingredients: Acrylic acid, Aluminum Hydroxide, Carmellose Sodium, 2-Ethylhexyl Acrylate, Glycerin, Isopropyl Myristate, Methyl Acrylate, Nonoxynol-30, Polyacrylate, Polyacrylic Acid, Polysorbate 80, Sorbitan Sesquileate, Starch, Talc, Tartaric Acid, Titanium Dioxide, Water(245-114)

Questions? 888 907-2833

Manufactured for: *Medi-Sulting.com*
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Made in China www.medi-derm.net
NDC 76074 123 21

MEDI-SULTING TOPICAL PAIN RELIEF

methyl salicylate menthol capsaicin lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76074-123
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	.035 g in 100 g

LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)

LIDOCAINE

0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ETHYLHEXYL ACETATE (UNII: 2C7K8OA8SB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
POLYACRYLIC ACID (800000 MW) (UNII: D0I6NSZ87U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76074-123-21	10 g in 1 PATCH; Type 0: Not a Combination Product	03/12/2015	

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)

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Two Hip Consulting, LLC