TOPICAL PAIN RELIEF- methyl salicylate, menthol, capsaicin cream
Unit Dose Services

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.

Topical Pain Relief

Active ingredients	Purpose
Methyl salicylate 20% (16gm)	Topical Analgesic
Menthol 5% (4gm)	Topical Analgesic
Capsaicin 0.035% (0.3gm)	Topical Analgesic

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.

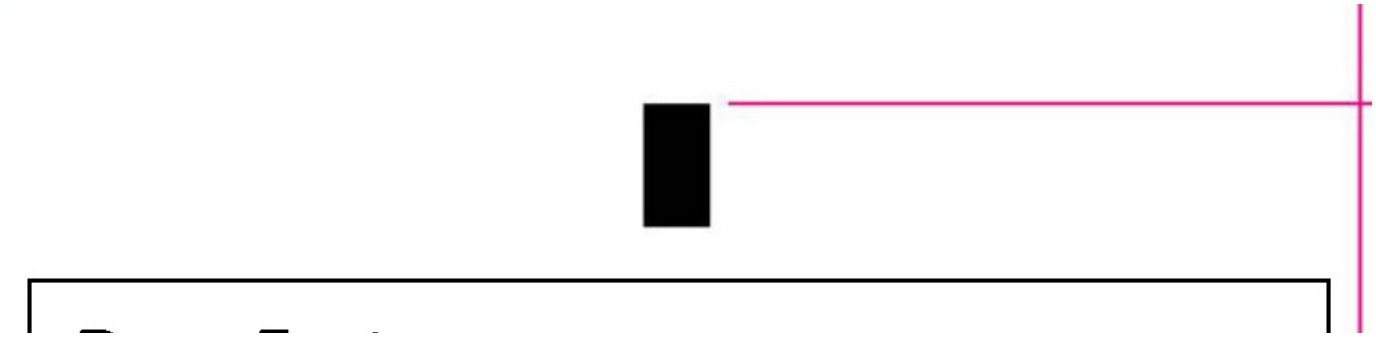
Keep out of reach of children

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.

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 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.

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.



Drug Facts

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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
NDC CODE 76074 120 01

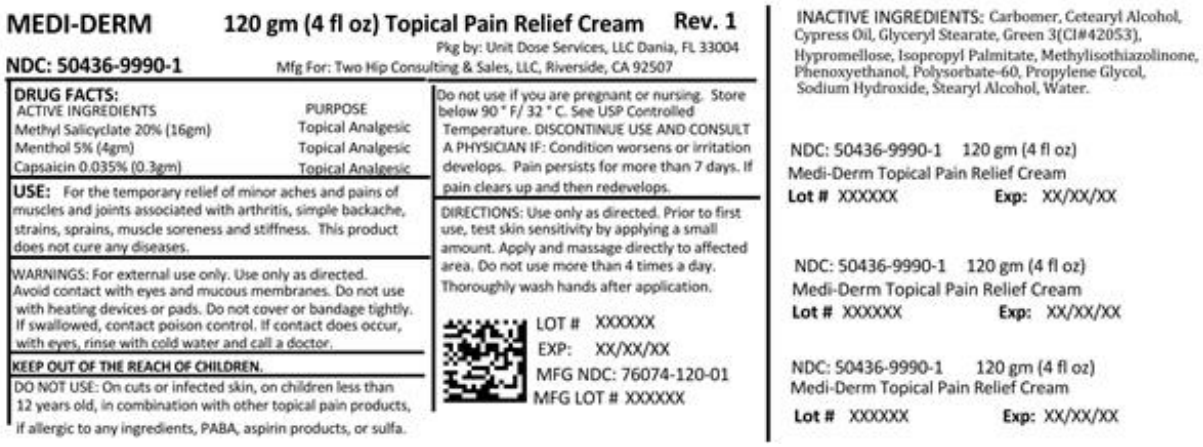
BACK PANEL

HOW SUPPLIED

Product: 50436-9990

NDC: 50436-9990-1 120 g in a BOTTLE

TOPICAL PAIN RELIEF (METHYL SALICYLATE, MENTHOL, CAPSAICIN) CREAM



TOPICAL PAIN RELIEF

methyl salicylate, menthol, capsaicin cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-9990(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 MPA.S) (UNII: VM7F0B23ZI)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-9990-1	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 - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-9990) , RELABEL(50436-9990)

Revised: 6/2018 Unit Dose Services