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.

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.

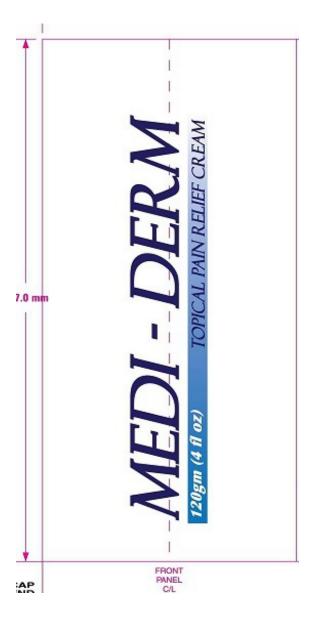
KEEP OUT OF REACH OF CHILDREN.

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, 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

Active ingredients

Purpose

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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

TOPICAL PAIN RELIEF

methyl salicylate, menthol, capsaicin cream

Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:76074-120	
Route of Administration	TOPICAL			

Active Ingredien	t/Active Moiety		
	Ingredient Name	Basis of Streng	th Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)		24LPZ) METHYL SALICYLA	TE 20 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	5 g in 100 g
CAPSAICIN (UNII: S07	O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	.0355 g in 100 g
Inactive Ingredie	nts		
Ingredient Name			
CARBO MER HO MO P	OLYMER TYPE B (ALLYL SUCROSE CROSSLINKEI)) (UNII: Z135WT9208)	
CETOSTEARYL ALC	OHOL (UNII: 2DMT128M1S)		
GLYCERYL MONOST	FEARATE (UNII: 230OU9XXE4)		
FD&C GREEN NO.3 (UNII: 3P3ONR6O1S)		
HYPROMELLOSE 22	08 (100000 MPA.S) (UNII: VM7F0B23ZI)		
ISOPROPYL PALMIT	ATE (UNII: 8 CRQ2TH6 3M)		
METHYLISOTHIAZO	LINONE (UNII: 229 D0 E1QFA)		
PHENO XYETHANO L	(UNII: HIE492ZZ3T)		
POLYSORBATE 60 (JNII: CAL22UVI4M)		
PROPYLENE GLYCO	L (UNII: 6DC9Q167V3)		
SO DIUM HYDRO XIDI	E (UNII: 55X04QC32I)		
STEARYL ALCOHOL	(UNII: 2KR89I4H1Y)		
WATER (UNII: 059QF0	VKO0R)		
Packaging			
# Item Code	Package Description	Marketing Start Date M	larketing End Dat
1 NDC:76074-120-01	120 g in 1 BOTTLE; Type 0: Not a Combination Product	0 1/15/20 11	
Marketing Inf			
Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat

Labeler - Two Hip Consulting, LLC (965352896)

Registrant - Two Hip Consulting, LLC (965352896)

Revised: 2/2019

Two Hip Consulting, LLC