#### DOLORACIN RX- methyl salicylate, menthol and capsaicin 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.

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Active ingredients

Capsaicin 0.035% 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, 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.

### **Drug Facts**

#### **Active ingredients**

#### Purpose

Capsaicin 0.035%	Topical Analgesic
Menthol 5%	Topical Analgesic
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

Hydroxido, 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 141 14

#### DOLORACIN RX

methyl salicylate, menthol and capsaicin cream

## **Product Information**

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:76074- 141
Route of Administration	TOPICAL	DEA Schedule	

#### Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (SALICYLIC ACID)	METHYL SALICYLATE	20 g in 100 mL	
MENTHOL (MENTHOL)	MENTHOL	5 g in 100 mL	
CAPSAICIN (CAPSAICIN)	CAPSAICIN	0.035 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER 934			
CETOSTEARYL ALCOHOL			
CYPERUS ESCULENTUS LEAF			
GLYCERYL MONOSTEARATE			
FD&C GREEN NO. 3			
HYPROMELLOSE 2208 (100000 MPA.S)			
ISOPROPYL PALMITATE			
METHYLISO THIAZO LINO NE			
PHENO XYETHANO L			
POLYSORBATE 60			
PROPYLENE GLYCOL			
SO DIUM HYDRO XIDE			
STEARYL ALCOHOL			
WATER			

Packaging				
# Item	Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76074	-141-14	120 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/11/2013	

# Labeler - Two Hip Consulting, LLC (965352896)

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

Revised: 9/2013 Two Hip Consulting, LLC