SMARTRX NATURAL PAIN RELIEF SLEEVE WRIST - methyl salicylate liquid Niche Brands, Inc.

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.

SmartRx Natural Pain Relief Sleeve WRIST

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Active ingredient

Methyl Salicylate 10%

Purpose

External Analgesic (Counterirritant)

Use

for the temporary relief of minor aches and pains of muscles and joints associated with • arthritis • strains • bruises • sprains.

Warnings

For external use only. Avoid contact with the eyes.

When using this product

- Do not use otherwise than as directed.
- Do not apply to wounds or damaged skin.
- Do not bandage tightly.
- Do not use in conjunction with liniments, balms or lotions.
- Do not use on damaged or broken skin.

Stop use and ask a doctor if

- Redness is present.
- Excessive irritation of skin develops.
- Condition worsens, or if symptoms persist for more than 7 days.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

if swallowed, get medical help or contact Poison Control Center right away.

Directions

Open pouch and remove. Pull woven sleeve containing external analgesic pads over ankle, positioning on either side of affected area.

• Adults and children 3 years of age and older: Apply to the affected area not more than 3 to 4 times

daily.

• Children under 3 years of age: Consult a physician.

Other information:

- Store away from direct sunlight.
- For your protection, this sleeve has been sealed in an aluminum pouch.
- Do not use if tamper evident seal is missing, tampered, broken or destroyed.

Allergy warning:

Contains Macadamia nut oil.

Inactive ingredients

Macadamia nut oil, citronella oil, mandarin oil, coriander oil and rosemary oil.

Questions?:

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SmartRx Natural Pain Relief Sleeve WRIST Small To Medium 1 count (60589-005-00) | SmartRx Natural Pain Relief Sleeve WRIST Large To X-Large 1 count (60589-005-01)

SMART

DELIVERS 2 IN 1 PENETRATING PAIN AND MOISTURIZING RELIEF

Clinical studies show the SMART**RX**^{IM} formula with 10% natural methyl salicylate is proven to reduce sensitivity to joint pain for immediate and effective comfort.

Comfortable, no mess

utomatically and contin leases ingredients to im mfort and mobility

Patented, Poly Matrix time-re technology reli

5 Natural Essential Oils penetrate deeply and moisturize effectively

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IDEAL FOR RELIEF OF DISCOMFORT FROM:

Working Out Gardening Sports

SMARTRx™ Natural Pain Relief Sleeve is also available for: Knees

Backs Elbows Ankles



SMART



THERAPEUTIC All Natural Essential Oil-Based Ingredients Deliver Targeted Soothing Relief

DEEP PENETRATING Relief From Muscle And Joint Discomfort That Lasts For Hours

COMFORTABLE Contoured-Fit Fabric Sleeve Conforms To Your Body For Targeted Relief

TOPICAL ANALGESIC-METHYL SALICYLATE (10%) LATEX FREE

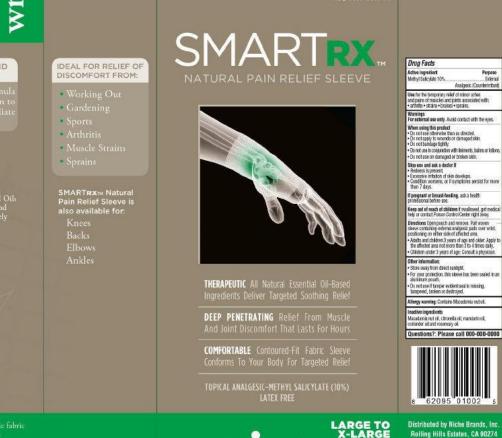




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SMARTRX NATURAL PAIN RELIEF SLEEVE WRIST

methyl salicylate liquid

CORIANDER OIL (UNII: 7626GC95E5) ROSEMARY OIL (UNII: 8LGU7VM393)

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sourc	NDC:60589-005			
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingredient Name				Basis of Strength		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)				METHYL SALICYLATE		
Inactive Ingredients						
Ingredient Name					Strength	
MACADAMIA OIL (UNII: 515610SU8C	2)					
CITRONELLA OIL (UNII: QYO8Q067	′D0)					
MANDARIN OIL (UNII: NJO720F72R)						

Packaging								
# Item Code	Package Description	Marketin	g Start Date M	arketing End Date				
1 NDC:60589-005-00	1 in 1 BOX							
1	0.2 g in 1 PACKAGE							
2 NDC:60589-005-01	1 in 1 BOX							
2	0.2 g in 1 PACKAGE							
Marketing Information								
0	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date				
Marketing Categor	y Application Number of Monog	/ 1						

Labeler - Niche Brands, Inc. (079208100)

Establishment						
Name	Address	ID/FEI	Business Operations			
AB7 Industries		381206077	manufacture(60589-005)			

Revised: 12/2013

Niche Brands, Inc.