

**SMARTRX NATURAL PAIN RELIEF SLEEVE ANKLE- 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.*

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**SmartRx Natural Pain Relief Sleeve ANKLE**

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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 ?:**

000-000-0000

**SmartRx Natural Pain Relief Sleeve ANKLE 1 count (60589-001-00)**

**SMARTRX™**  
NATURAL PAIN RELIEF SLEEVE

**ankle**

**DELIVERS 2 IN 1 PENETRATING PAIN AND MOISTURIZING RELIEF**

Clinical studies show the SMARTRX™ formula with 10% natural methyl salicylate is proven to reduce sensitivity to joint pain for immediate and effective comfort.

Comfortable, no mess delivery system

Automatically and continuously releases ingredients to improve comfort and mobility

5 Natural Essential Oils penetrate deeply and moisturize effectively

Patented, Polymer-Matrix time-release technology relieves pain upon contact

Washable, expandable elastic fabric is reusable for up to 7 times over a 30 day period

**IDEAL FOR RELIEF OF DISCOMFORT FROM:**

- Working Out
- Gardening
- Sports
- Arthritis
- Muscle Strains
- Sprains

**SMARTRX™ Natural Pain Relief Sleeve is also available for:**

- Backs
- Wrists
- Elbows
- Knees

**SMARTRX™**  
NATURAL PAIN RELIEF SLEEVE

**ankle**

**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

**ONE SIZE FITS MOST**

**ankle**

ONE SLEEVE IN FOIL PACKAGE (3.84 OZ)

**Drug Facts**

Active ingredient	Purpose
Methyl Salicylate 10%	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 across sleeve containing external analgesic pads over ankle, positioning on either side of affected area.

- Adults and children 2 years of age and older: Apply to the affected area not more than 3 to 4 times daily.
- Children under 2 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?: Please call 000-000-0000**

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Distributed by Niche Brands, Inc.  
Rolling Hills Estates, CA 90274  
www.SmartRxPainRelief.com  
Product of France

# SMARTRX NATURAL PAIN RELIEF SLEEVE ANKLE

methyl salicylate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60589-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
MACADAMIA OIL (UNII: 515610SU8C)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
MANDARIN OIL (UNII: NJO720F72R)	
CORIANDER OIL (UNII: 7626GC95E5)	
ROSEMARY OIL (UNII: 8LGU7VM393)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60589-001-00	1 in 1 BOX		
1		0.2 g in 1 PACKAGE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/27/2013	

**Labeler** - Niche Brands, Inc. (079208100)

## Establishment

Name	Address	ID/FEI	Business Operations
AB7 Industries		381206077	manufacture(60589-001)

Revised: 12/2013

Niche Brands, Inc.