

SMARTRX NATURAL PAIN RELIEF SLEEVE BACK- 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 BACK

SmartRx Natural Pain Relief Sleeve BACK

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

Product Label

SMARTRX™
NATURAL PAIN RELIEF SLEEVE

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:

- Knees
- Wrists
- Elbows
- Ankles

SMARTRX™
NATURAL PAIN RELIEF SLEEVE

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

back

ONE SLEEVE IN FOIL PACKAGE (3.84 OZ)

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Stop use and ask a doctor if:

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- 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 over sleeve containing external analgesic pads over back, 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 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?: 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

methyl salicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60589-002
Route of Administration	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:60589-002-00	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(60589-002)

Revised: 12/2013

Niche Brands, Inc.