

SMARTRX NATURAL PAIN RELIEF SLEEVE ELBOW - 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 ELBOW

SmartRx Natural Pain Relief Sleeve ELBOW

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 ELBOW 1 count (60589-003-00)

SMARTRX™ elb
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:

Ankles
Wrists
Backs
Knees

NDC 0000-0000-00

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

Drug Facts

| Active ingredient | Purpose |
|-----------------------|--------------------------------------|
| Methyl Salicylate 10% | External Analgesic (Counterirritant) |

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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 woven sleeve containing external analgesic pads over elbow, 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.
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Questions?: Please call 000-000-0000




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elbow

ONE SLEEVE IN FOIL PACKAGE (3.84 OZ)

ONE SIZE FITS MOST



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

SMARTRX NATURAL PAIN RELIEF SLEEVE ELBOW

methyl salicylate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60589-003 |
| 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:60589-003-00 | 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(60589-003) |

Revised: 12/2013

Niche Brands, Inc.