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

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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.

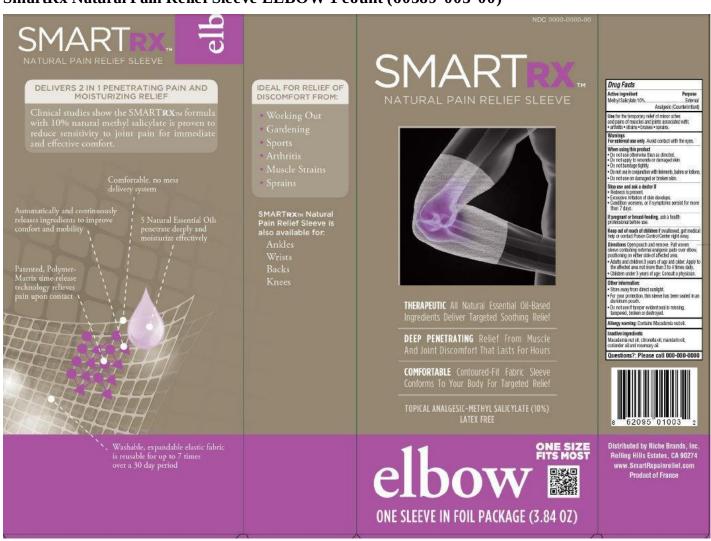
Inactive ingredients

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

Questions?:

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SmartRx Natural Pain Relief Sleeve ELBOW 1 count (60589-003-00)



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: LA	V5U5022Y) (SALICYLIC ACID - UNII:	O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

Inactive Ingredients Ingredient Name Strength MACADAMIA OIL (UNII: 515610SU8C) CITRO NELLA OIL (UNII: QY08Q067D0) MANDARIN OIL (UNII: NJ0720F72R)

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 38 1206077 manufacture(60589-003)

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