

SMARTRX NATURAL PAIN RELIEF SLEEVE KNEE - 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 KNEE

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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.

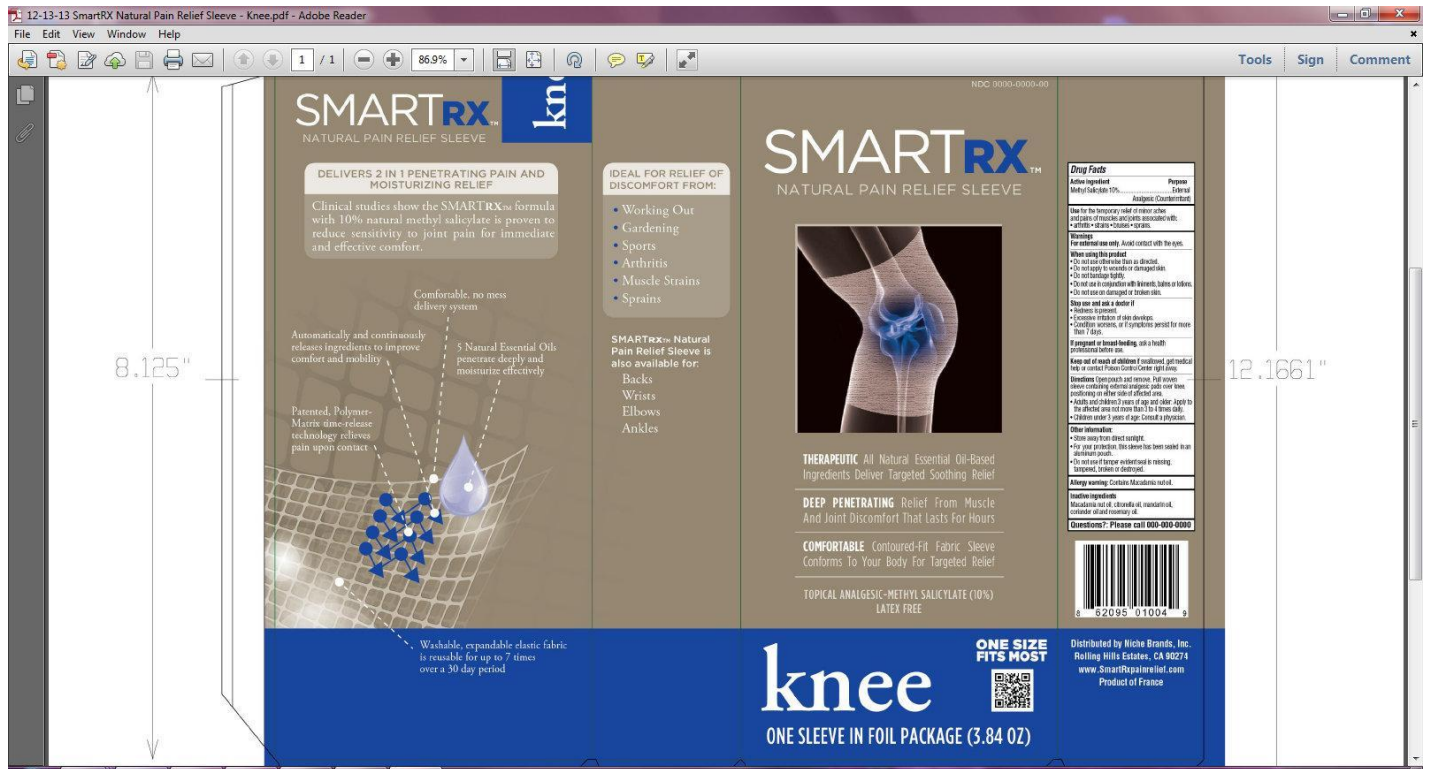
Inactive ingredients

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

Questions ?:

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SmartRx Natural Pain Relief Sleeve KNEE 1 count (60589-004-00)



SMARTRX NATURAL PAIN RELIEF SLEEVE KNEE

methyl salicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60589-004
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:60589-004-00	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(60589-004)

Revised: 12/2013

Niche Brands, Inc.