NUFABRX KNEE SLEEVE- capsaicin cloth Textile-Based Delivery, 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.

Nufabrx Knee Sleeve

Active Ingredient

Synthetic Capsaicin 0.15%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with: simple backache, arthritis, strains, bruises, and sprains.

Warnings

For external use only

Do not use

If you are allergic to any ingredients of this product or chili peppers contact a doctor before use (allergy alert)

On wounds or to damaged skin

With, or at same time as, other external analgesic products

With a heating pad

When using this product

- You may experience a burning sensation which is normal and related to the way the product works (with regular use, this sensation generally diminishes)
- Do not use immediately before or after activities such as swimming, showering, sunbathing or intense exercise
- Use only as directed
- Avoid contact with eyes and mucous membranes or rashes

Stop use and ask a doctor if

- Condition worsens, symptoms persist more than 7 days or clear up and occur again within a few days
- Rash, itching or excessive skin irritation develops

If pregnant or breastfeeding

Consult a healthcare professional before use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Clean and dry affected area
- Remove sleeve from packaging and place on knee
- Maximum use of 8 hours per day (remove after 8 hours of wear)
- Wash separately from other clothing
- Do not wear more than 6 days straight without doctor consent

Other Information

Avoid storing product in direct sunlight. Protect product from excessive moisture

Inactive Ingredients

Acrylates Copolymer

Principal Display Panel





WASH HANDS AFTER APPLYING

93% Nylon | 7% Spandex

Drug Facts

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Inactive Ingredients Acrylate copolymer

NUFABRX KNEE SLEEVE

capsaicin cloth

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72490-012

Route of Administration

TOPICAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.15			

Inactive Ingredients	
Ingredient Name	Strength
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:72490-012-03	1 in 1 POUCH; Type 0: Not a Combination Product	05/11/2020	

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part348	05/11/2020					

Labeler - Textile-Based Delivery, Inc. (079309716)

Revised: 5/2020 Textile-Based Delivery, Inc.