NUFABRX FOOT/ANKLE SLEEVE- capsaicin cloth Nufabrx LLC

Nufabrx Foot/Ankle Sleeve 72490-010

Active Ingredient

Capsaicin (Nonivamide) 0.12%

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 foot
- 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



NUFABRX FOOT/ANKLE SLEEVE

capsaicin cloth

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72490-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength | |
|-----------------|-------------------|----------|--|
| | | | |

CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM) CAPSAICIN 0.12 g in 100 g

Inactive Ingredients

| gredient Name | Strength |
|---------------|----------|

BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII:

JZ1374NL9E)

Packaging

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|---|------------------|---|-------------------------|-----------------------|
| | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:72490-010- | 1 g in 1 BOX; Type 0: Not a Combination Product | 05/11/2020 | |

Marketing Information

| Marketing III | il Oi illacioii | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M017 | 05/11/2020 | |

Labeler - Nufabrx LLC (119110776)

Registrant - Biotech Research Group (099152813)

Revised: 6/2024 Nufabrx LLC