

RUGBY CAPSAICIN CREAM- capsaicin cream

Rugby Laboratories

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.

Rugby Capsaicin Cream

Drug Facts

Active Ingredient

Capsaicin 0.1%

Purpose

Topical Analgesic

Warnings

For external use only: TEST FIRST ON SMALL AREA OF SKIN.

When using this product:

- Use only as directed
- Do not apply to wounds, damaged, broken or irritated skin
- Do not use if you are allergic to capsaicin or chili peppers
- Avoid contact with the eyes or mucous membranes
- A slight burning sensation may occur upon application, but generally disappears after several days of use
- If severe burning occurs, discontinue use
- Do not expose the treated area to heat or direct sunlight
- Do not bandage
- Do not use with heating pad

Stop Use and Ask Doctor

Stop Use and Ask Doctor if:

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present
- irritation develops

Keep Out of the Reach of Children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- Arthritis
- Simple Backache
- Strains
- Sprains
- Bruises

If Pregnant or Breast Feeding

Ask a doctor before use

Directions

Adults and Children over 18 years:

- Apply to affected area
- Massage into the painful area until thoroughly absorbed
- Repeat as necessary but not more than 3 to 4 times daily
- WASH HANDS WITH SOAP AND WATER AFTER APPLYING

Children 18 years and younger:

Ask a doctor

Inactive Ingredients

Aloe barbadensis leaf juice, Cetostearyl alcohol, Ethylparaben, Glycerin, Glyceryl monostearate, Mineral Oil, Petrolatum, Polyoxyethylene lauryl ether, Purified Water, stearic acid.

Questions

Call 1-800-645-2158

Distributed By:

RUGBY® LABORATORIES

Livonia, MI 48152

www.rugbylaboratories.com

rev. 09/21 R-167 Re-order No. 370818

Other Information

Store at room temperature 15°-30°F (59°-86°F)

Packaging

OUTSIDE BOX



INNER TUBE



capsaicin cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0536-1264 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ETHYLPARABEN (UNII: 14255EXE39) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| LAURETH-15 (UNII: 002FR4N8OV) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:0536-1264-56 | 1 in 1 BOX | 02/17/2020 | |
| 1 | | 42.5 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part348 | 02/17/2020 | |

Labeler - Rugby Laboratories (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)