

RUGBY CAPSAICIN CREAM- capsaicin cream
Rugby Laboratories

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: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	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 Drug	M017	02/17/2020	

Labeler - Rugby Laboratories (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)