

RUGBY CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream
medsource pharmaceuticals

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

External Analgesic

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

External analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints due to:

- simple backache
- arthritis
- strains
- sprains

Warnings

For external use only

Read all warnings and directions before use. Test first on small area of skin.

Do not use

- on wounds or damaged skin
- if you are allergic to capsicum or chili peppers

When using this product

- you may experience a burning sensation. The intensity of this reaction varies among individuals and may be severe. With regular use, this sensation generally disappears after several days.
- avoid contact with the eyes, lips, nose and mucous membranes
- do not tightly wrap or bandage the treated area
- do not apply heat to the treated area immediately before or after use

Stop use and ask a doctor if

- condition worsens or does not improve after regular use
- severe burning persists or blistering occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children 18 years of age and older:

- apply a thin film of cream to affected area and gently rub in until fully absorbed
- unless treating hands, wash hands thoroughly with soap and water immediately after application
- for best results, apply 3 to 4 times daily.

Children under 18 years: ask a doctor

Other information

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

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, cetyl acetate, methylparaben, PPG-20 methyl glucose ether distearate, propylene glycol, propylparaben, stearate-100, stearic acid, stearyl alcohol, triethanolamine, water

Questions or comments?

Call 1-800-645-2158 9 am - 5 pm ET, Monday - Friday

Mfd for:

Rugby Laboratories, Inc.
Duluth, Georgia 30097

PRINCIPAL DISPLAY PANEL



RUGBY CAPSAICIN EXTERNAL ANALGESIC

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45865-773(NDC:0536-2525)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CETYL ACETATE (UNII: 4Q43814HXS)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PPG-20 METHYL GLUCOSE ETHER DISTEARATE (UNII: 0057334FAB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
STEARETH-100 (UNII: 4OH5W9UM87)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45865-773-01	1 in 1 CARTON	06/01/2018	
1		60 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	03/01/2012	

Labeler - medsource pharmaceuticals (833685915)

Registrant - Garcoa, Inc. (103039178)

Establishment

Name	Address	ID/FEI	Business Operations
medsource pharmaceuticals		833685915	relabel(45865-773)