CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream NuCare Pharmaceuticals, 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.

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

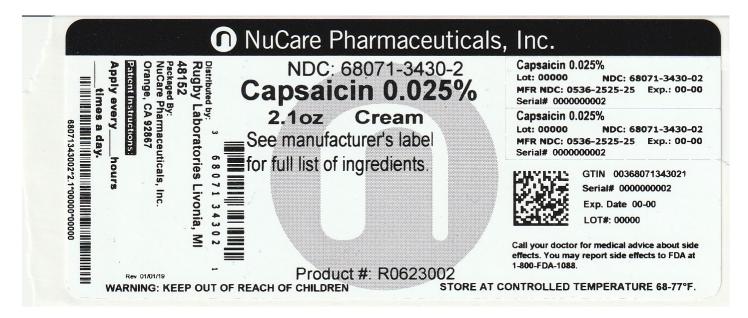
acrylates/C10-30 alkyl acrylate crosspolymer, cetyl acetate, methylparaben, PPG-20 methyl glucose ether distearate, propylene glycol, propylparaben, stearate-100, stearic acid, stearyl alcohol, triethanolamine, water

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



CAPSAICIN EXTERN	IAL ANALGES	SIC						
capsaicin cream								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:68071-3430(N		0(NDC:0536-2525)				
Route of Administration	TOPICAL							
Active Ingredient/Active	Moiety							
	lient Name		Basis of Strength	Strength				
-	CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM) CAPSAICIN 0.2							
Inactive Ingredients								
	Ingredient	Name		Strengt				
CARBOMER COPOLYMER TYPE	A (ALLYL PENTAERY	THRITOL CROSSLII	NKED) (UNII: 71DD5V99	95L)				
CETYL ACETATE (UNII: 4Q43814	HXS)							
METHYLPARABEN (UNII: A218C7H	•							
PPG-20 METHYL GLUCOSE ETH		II: 0057334FAB)						
PROPYLENE GLYCOL (UNII: 6DC								
PROPYLPARABEN (UNII: Z8IX2SC								
STEARETH-100 (UNII: 40H5W9UI								
STEARIC ACID (UNII: 4ELV7Z65AP)								
STEARYL ALCOHOL (UNII: 2KR89	14H1Y)							
TROLAMINE (UNII: 903K93S3TK)								
WATER (UNII: 059QF0K00R)								
Product Characteristics	· · · · · · · · · · · · · · · · · · ·							
Color	white	Score						
Shape		Size						

Flavor		Imprint	Imprint Code						
Contains									
Pa	ackaging								
#	Item Code	Pack	Package Description		Marketing Start Date	Marketing End Date			
1	NDC:68071- 3430-2	1 in 1 CARTON	n 1 CARTON		6/07/2023				
1		60 g in 1 TUBE; Product	Type 0: Not a Combination						
Marketing Information									
Marketing Applicati Category		Applicati	on Number or Monograph Citation		Marketing Start Date	Marketing End Date			
OT fin	C monograph not al	part348			03/01/2012				

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment									
Name	Address	ID/FEI	Business Operations						
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-3430)						

Revised: 6/2023

NuCare Pharmaceuticals, Inc.