

CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream
NuCare Pharmaceuticals, Inc.

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

 **NuCare Pharmaceuticals, Inc.**

NDC: 68071-3430-2
Capsaicin 0.025%
2.1oz Cream
See manufacturer's label
for full list of ingredients.

Capsaicin 0.025%
Lot: 00000 NDC: 68071-3430-02
MFR NDC: 0536-2525-25 Exp.: 00-00
Serial# 0000000002

Capsaicin 0.025%
Lot: 00000 NDC: 68071-3430-02
MFR NDC: 0536-2525-25 Exp.: 00-00
Serial# 0000000002

 GTIN 00368071343021
Serial# 0000000002
Exp. Date 00-00
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Product #: R0623002

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

Distributed by: 3 68071 34302 1
Rugby Laboratories Livonia, MI
48152
Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Apply every _____ hours
times a day.

Rev 01/01/19

68071343002-2-1-00000-00000

CAPSAICIN EXTERNAL ANALGESIC

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-3430(NDC:0536-2525)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CETYL ACETATE (UNII: 4Q43814HXS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PPG-20 METHYL GLUCOSE ETHER DISTEARATE (UNII: 0057334FAB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARETH-100 (UNII: 4OH5W9UM87)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
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:68071-3430-2	1 in 1 CARTON	06/07/2023	
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 Drug	M017	03/01/2012	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

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

Revised: 2/2025

NuCare Pharmaceuticals,Inc.