

**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.*

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**Rugby<sup>®</sup> 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.

88071343002-1-00000-00000

Apply every \_\_\_\_\_ hours  
\_\_\_\_\_ times a day.

Rev 01/01/19

48152  
Packaged By:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867

Distributed by:  
3 6807134302 1  
Rugby Laboratories Livonia, MI

Patient Instructions:

## 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	

<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
1	NDC:68071-3430-2	1 in 1 CARTON	06/07/2023
1		60 g in 1 TUBE; Type 0: Not a Combination Product	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	03/01/2012	

**Labeler** - NuCare Pharmaceuticals,Inc. (010632300)

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