

## **RUGBY CAPSAICIN EXTERNAL ANALGESIC- capsaicin cream**

**Rugby Laboratories, 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® 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 - 60 g Tube Carton**

NDC 0536-2525-25

**Rugby**<sup>®</sup>

SATISFACTION GUARANTEED

**Rugby**

OR YOUR MONEY BACK

**Capsaicin Cream, 0.025%**

External Analgesic

Penetrating Pain Relief

Net Wt 2.1 oz (60 g)



NDC 0536-2525-25



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N 3 0536-2525-25 4

Mfd for:

Rugby Laboratories, Inc.

Duluth, Georgia 30097

www.rugbylaboratories.com

R1211

07-057 Made in Canada

## Drug Facts (continued)

**Do not use** ● on wounds or damaged skin ● if you are allergic to capsaicin 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

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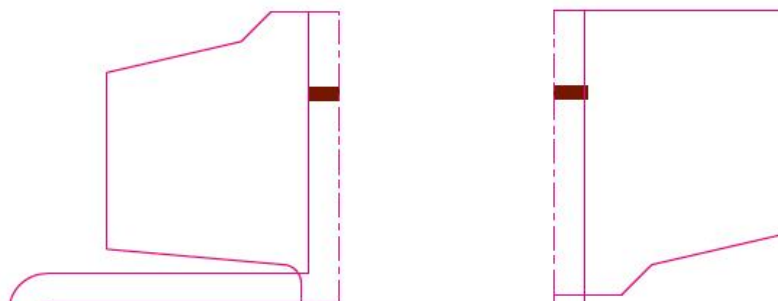
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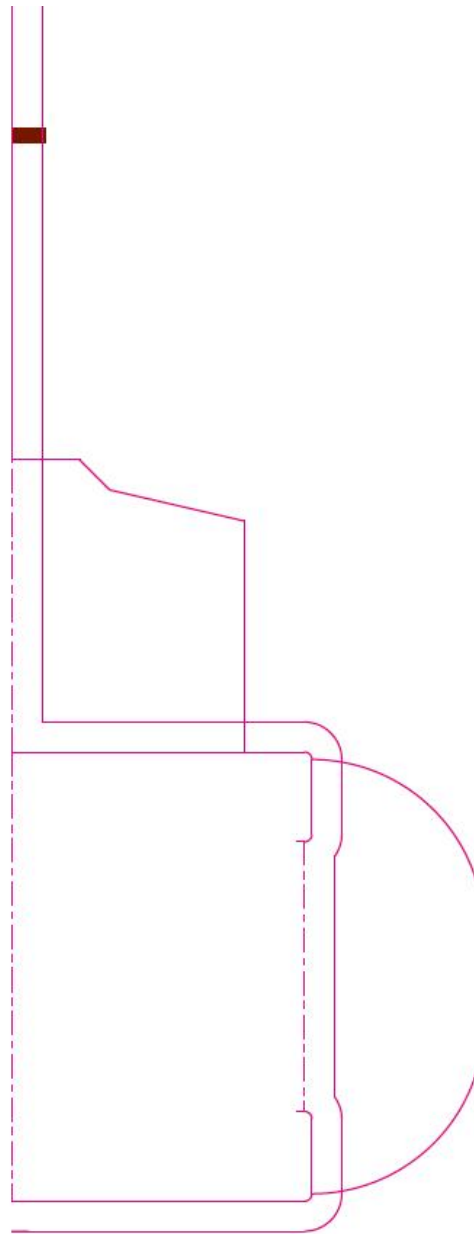
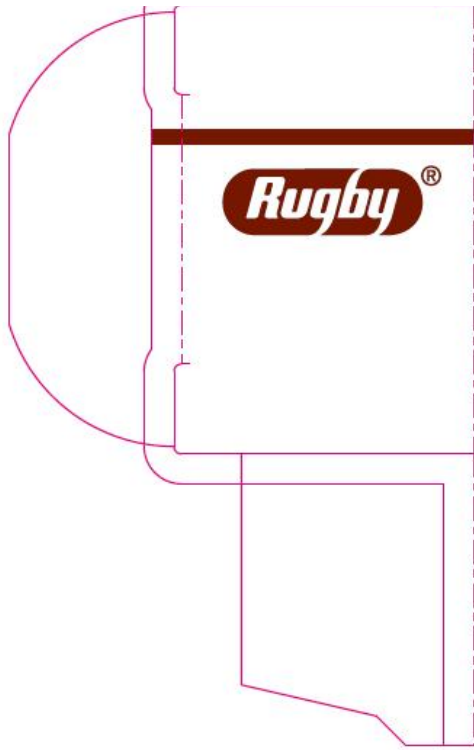
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## RUGBY CAPSAICIN EXTERNAL ANALGESIC

capsaicin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-2525
<b>Route of Administration</b>	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
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<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>Cetyl Acetate</b> (UNII: 4Q43814HXS)	
<b>Methylparaben</b> (UNII: A28C7H9T)	
<b>PPG-20 Methyl Glucose Ether Distearate</b> (UNII: 0057334FAB)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Steareth-100</b> (UNII: 4OH5W9UM87)	
<b>Stearic Acid</b> (UNII: 4ELV7Z65AP)	
<b>Stearyl Alcohol</b> (UNII: 2KR89I4HIY)	
<b>Trolamine</b> (UNII: 9O3K93S3TK)	
<b>Water</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-2525-25	1 in 1 CARTON		
1		60 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	03/01/2012	

**Labeler** - Rugby Laboratories, Inc. (191427277)

**Registrant** - Garcoa, Inc. (103039178)

### Establishment

Name	Address	ID/FEI	Business Operations
Garcoa, Inc.		103039178	MANUFACTURE(0536-2525)