

CAPSAICIN- capsaicin cream
Rugby Laboratories

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®

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)

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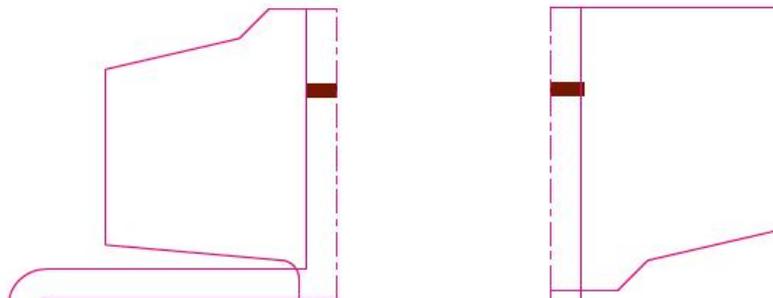
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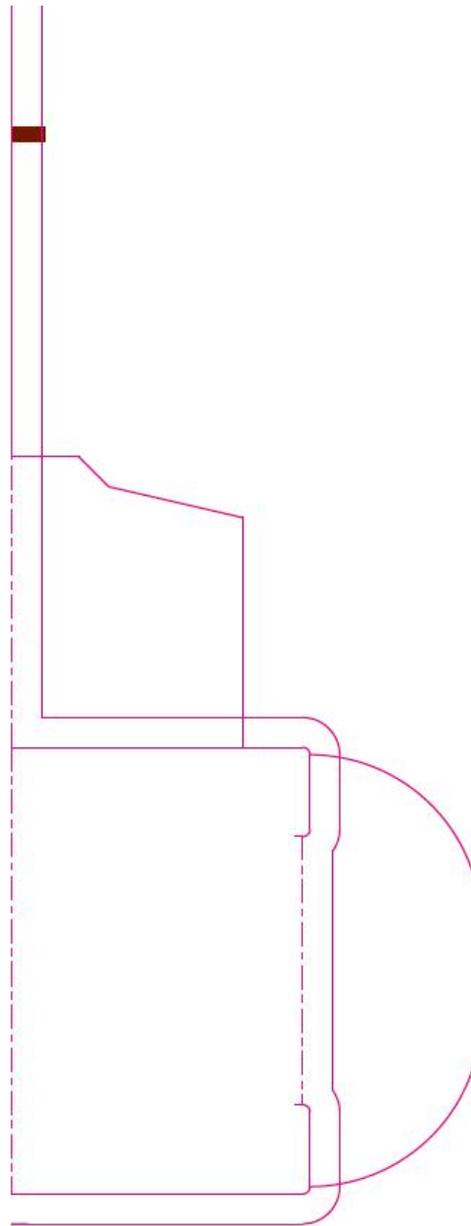
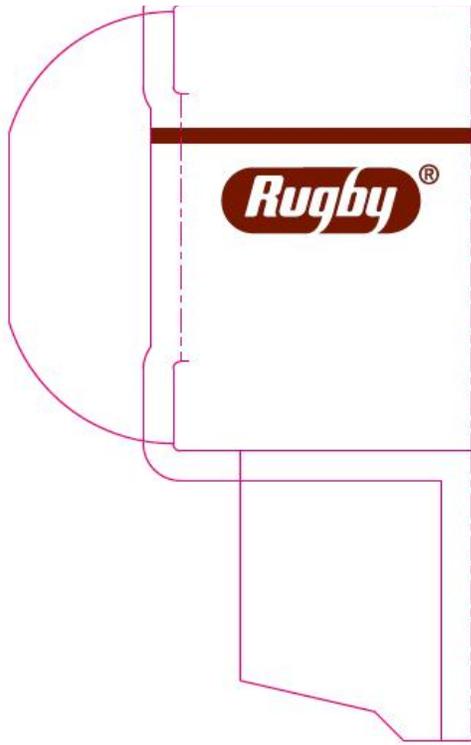
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CAPSAICIN

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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:0536-2525-25	1 in 1 CARTON	03/01/2012	
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 - Rugby Laboratories (079246066)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
SV Labs Toronto Corporation		203917476	manufacture(0536-2525)