

## **RUGBY ARTHRITIS PAIN RELIEVING TOPICAL ANALGESIC- capsaicin cream**

### **Rugby Laboratories**

*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® Arthritis Pain Relieving Cream**

#### **Drug Facts**

##### **Active ingredient**

Capsaicin 0.075%

##### **Purpose**

Topical 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 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 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.

**If pregnant or breast feeding**, ask a health professional before use.

### **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°F – 86°F).

### **Inactive ingredients**

benzyl alcohol, cetyl alcohol, glyceryl stearate, isopropyl myristate, PEG-100 stearate, petrolatum, sorbitol, water

### **Questions or comments?**

**1-800-645-2158**

Distributed by: Rugby Laboratories  
17177 N Laurel Park Dr., Suite 233  
Livonia, MI 48152

**PRINCIPAL DISPLAY PANEL - 57 g Tube Carton**

NDC 0536-1118-25

**Rugby®**

**COMPARE TO  
ZOSTRIX® HP  
ACTIVE INGREDIENT\***

**HIGH POTENCY  
ARTHRITIS PAIN RELIEVING CREAM  
0.075% CAPSAICIN TOPICAL ANALGESIC**

**Odor Free Formula • Clinically Tested Active Ingredient  
Net Wt 2 oz (57 g)**



## RUGBY ARTHRITIS PAIN RELIEVING TOPICAL ANALGESIC

capsaicin cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1118
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.75 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Benzyl Alcohol (UNII: LKG8494WBH)	
Cetyl Alcohol (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
PEG-100 Stearate (UNII: YD01N1999R)	
Petrolatum (UNII: 4T6H12BN9U)	

**Sorbitol** (UNII: 506T60A25R)

**Water** (UNII: 059QF0KO0R)

### 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:0536-1118-25	1 in 1 CARTON	05/24/2017	
1		57 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 NOT FINAL	part348	05/24/2017	

**Labeler** - Rugby Laboratories (079246066)

**Registrant** - Garcoa, Inc (036464697)

### Establishment

Name	Address	ID/FEI	Business Operations
Garcoa, Inc		036464697	MANUFACTURE(0536-1118)

Revised: 5/2017

Rugby Laboratories