# **RUGBY LIDOCAINE- lidocaine cream RUGBY**

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® LIDOCAINE 4%**

#### **Drug Facts**

### **Active ingredient**

Lidocaine 4%

### **Purpose**

Topical analgesic

#### Use

for the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations

### **Warnings**

For external use only.

Avoid contact with eyes.

Not for prolonged use.

Do not use in large quantities, particularly over raw surfaces or blistered areas.

### Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days
- rash or irritation develops, persists, or increases

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

#### **Directions**

Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily

### Children under 2 years of age: Consult a doctor

#### Other information

- store at 15 to 30°C (59 to 86°F)
- This package is child-resistant

#### **Inactive ingredients**

aloe barbadensis leaf juice, arginine, benzophenone-4, caprylyl glycol, cetyl alcohol, dimethyl sulfoxide, hexylene glycol, melaleuca alternifolia (tea tree) leaf oil, phenoxyethanol, potassium sorbate, purified water, simmondsia chinensis (jojoba) seed oil, sodium polyacrylate, stearic acid

#### Questions or comments?

1-800-645-2158

Distributed by:

**RUGBY® LABORATORIES** 

Livonia, MI 48152

### PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

Rugby®

Maximum Strength Lidocaine 4% Pain and Itch Relief Cream

NDC 0536-1278-03

Compare to the active ingredient in Gold Bond® with 4% Lidocaine\*

NET WT 0.52 OZ (15 g)

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PL10405B V02





\*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Gold Bond® with 4% Lidocaine.

Questions or comments? 1-800-645-2158

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Drug Facts (continued)

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### **RUGBY LIDOCAINE**

lidocaine cream

#### **Product Information**

**Product Type HUMAN OTC DRUG Item Code (Source)** NDC:0536-1278

**Route of Administration TOPICAL** 

### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 40 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			

ARGININE (UNII: 94Z LA3W45F)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ANGOPHORA COSTATA WHOLE (UNII: O5MY197D8F)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
WATER (UNII: 059QF0KO0R)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

I	Packaging							
4	tem Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:0536-1278- 03	1 in 1 CARTON	01/17/2020					
:		15 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	01/17/2020				

## **Labeler -** RUGBY (079246066)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Natureplex LLC		062808196	MANUFACTURE(0536-1278)		

Revised: 9/2021 RUGBY