

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.

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)



RUGBY LIDOCAINE		
lidocaine cream		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	TOPICAL	NDC:0536-1278
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: 94ZLA3W45F)
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: 05I15JN12J)
STEARIC ACID (UNII: 4ELV7Z65AP)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1278-03	1 in 1 CARTON	01/17/2020	
1		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	Business Operations
Natureplex LLC		062808196	MANUFACTURE(0536-1278)

Revised: 9/2021

RUGBY