

RUGBY LIDOCAINE- lidocaine 4% 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.

Rugby Lidocaine Cream

Lidocaine 4%

Local Anesthetic

Uses

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

For external use only.

When using this product avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if rectal bleeding occurs, condition worsens or does not improve within 7 days, allergic reaction occurs to ingredients in this product, symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, or symptoms clear up and return within a few days.

If pregnant or breastfeeding, ask a professional before use.


Keep out of reach of the children. If swallowed, get medical help or contact a Poison Control Center right away.

- When practical, cleanse the area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.

Butylated Hydroxytoluene, Cetostearyl Alcohol, Citric Acid, Edetate Disodium, Light Mineral Oil, Methylparaben, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, White Petrolatum.

LOT #
EXP. DATE

Rev. 02/22 R-177 Re-order No. 37116



3 05361 135795 5

Drug Facts (continued)

Directions

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.

Other information Store at 15°-30° C (59°-86° F)

Inactive ingredients butylated hydroxytoluene, cetostearyl alcohol, citric acid, edetate disodium, light mineral oil, methylparaben, polyoxyl 20 cetostearyl ether, propylene glycol, propylparaben, purified water, sodium citrate, white petrolatum

Drug Facts (continued)


Questions or comments? 1-800-645-2158

Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
www.rugbylaboratories.com

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

KEEP OUT OF REACH OF CHILDREN.

NDC 0536-1357-95



Lidocaine Cream

Lidocaine 4%

Local Anesthetic

NET WT 1 OZ (28 g)

NET WT 1 OZ (28 g)

Local Anesthetic

4%

Lidocaine Cream

Lidocaine



NDC 0536-1357-95

Local Anesthetic

Lidocaine Cream

Lidocaine 4%

Drug Facts

Active ingredient Lidocaine 4% **Purpose** Local anesthetic

Uses Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders

Warnings
For external use only
When using this product • avoid contact with eyes • do not exceed recommended dosage unless directed by a doctor • do not put this product into the rectum

Drug Facts (continued)

by using fingers or any mechanical device or applicator

Stop use and ask a doctor if • rectal bleeding occurs • condition worsens or does not improve within 7 days • allergic reaction occurs to ingredients in this product • symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase • symptoms clear up and return within a few days

If pregnant or breastfeeding, 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 (1-800-222-1222).

RUGBY LIDOCAINE

lidocaine 4% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1357
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1357-95	1 in 1 BOX	03/02/2022	
1		28 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	03/02/2022	

Labeler - Rugby Laboratories (079246066)

Revised: 3/2022

Rugby Laboratories